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ELECTRONIC HEALTH RECORD (EHR) STANDARDS FOR INDIA

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Standards Set Recommendations v2.0

TABLE OF CONTENTS

Contents

Executive Summary 1
Standards at a Glance 3
Standards and Interoperability 7
Health Record IT Standards 9
Guidelines 16
Data Ownership of Health Records 18
Data Privacy and Security 23
Glossary 28
Contact Information 44

Executive Summary

INTRODUCTION

In September 2013 the Ministry of Health & Family Welfare (MoH&FW) notified the Electronic Health Record (EHR) Standards for India. The set of standards given therein were chosen from the best available and used standards applicable to Electronic Health Records from around the world keeping in view their suitability and applicability in India. The Committee constituted to recommend the standards drew from experts, practitioners, government officials, technologists, and industry. The notified standards were not only supported by professional bodies, regulatory bodies, stakeholders, but various technical and social commentators as well as being a step in the right direction. MoH&FW moved ahead with facilitating the adoption, as next steps, and in last two years the Ministry has made available standards like SNOMED CT free for use in country as well as appoint interim National Release Center (NRC) to handle this clinical terminology standard that is fast gaining widespread acceptance amongst the various healthcare IT stakeholder communities worldwide.

At the time of notifying the standards in September 2013, it was understood that the standards themselves will continue to evolve over time. Consequently, it was accepted that this notification will require revision from time to time. This becomes all the more necessary as understanding of those standards, their implementation and the expectations from the healthcare systems improve. Hence, MoH&FW constituted an expert group to review the earlier notified set of standards based on the experience and eyes firmly on the future. The set of standards provided herein represents the recommendations of the Expert Committee arrived at after deliberating on the various aspects of standardizations in healthcare record systems. The Committee also carefully examined the provisions of open standards and the guidelines as per the norms suggested by DeitY, MCIT, Government of India and recommended the standards given later in the document.

NEED FOR ELECTRONIC HEALTH RECORD

For a health record of an individual to be clinically meaningful it needs to be from conception or birth, at the very least. As one progresses through one's life, every record of every clinical encounter represents a health-related event in one's life. Each of these records may be insignificant or significant depending on the current problems that the person is suffering from. Thus, it becomes imperative that these records be available, arranged, and be clinically relevant to provide a summary of the various clinical events in the life of a person.

An Electronic Health Record (EHR) is a collection of various medical records that get generated during any clinical encounter or events. With rise of self-care and homecare devices and systems, meaningful healthcare data get generated 24x7 and also have long-term clinical relevance. The purpose of collecting medical records, as much as possible, are manifold – better and evidence based care, increasingly accurate and faster diagnosis that translates into better treatment at lower costs of care, avoid repeating unnecessary investigations, robust analytics including predictive analytics to support personalized care, improved health policy decisions based on better understanding of the underlying issues, etc., all translating into improved personal and public health.

EXECUTIVE SUMMARY

Without standards, a lifelong medical record is simply not possible, as different records from different sources spread across ~80+ years potentially needs to be brought meaningfully together. To achieve this, a set of pre-defined standards for information capture, storage, retrieval, exchange, and analytics that includes images, clinical codes and data is imperative.

STRATEGIC HIGHLIGHTS

This document provides a structured overview of the key EHR standards with respect to Indian healthcare system. For every aspect of data/information that is part of any healthcare record system has been addressed with a short guideline regarding implementation included. Various non-related recommendations from previous edition have been removed to better streamline the set of standards selected and achieve harmony among them. A detailed recommendation on the interoperability and standards, clinical informatics standards, data ownership, privacy and security aspects, and the various coding systems are given. The set of standards given in earlier edition has been updated with their latest versions as we move towards a better implementation.

SCOPE

This document provides a set of recommendations relevant to adoption of electronic health informatics standards in EHR/EMR and other similar clinical information systems. The scope is limited to identifying the standards, their intended purposes in such systems, and a short guideline for implementation approach. It is understood that with adoption of these standards properly, the data capture, storage, view, presentation, and transmission will be standardized to level that will achieve interoperability of both meaning and data contained in clinical records. This document does not cater to wider implementation scenarios such as of administrative, legal or regulatory nature. This document also does not cater to aspects of creation and operation of local, regional or national infrastructures, indexes, or repositories as they are dealt with by appropriate regulative/administrative body.

LOOKING AHEAD

This document is a continuation of its earlier version, but in many ways reflects our growing confidence in path correctly chosen earlier – set of international and proven standards focused towards syntactic and semantic interoperability. The idea that any person in India can go to any health service provider/practitioner, any diagnostic center or any pharmacy and yet be able to access and have fully integrated and always available health records in an electronic format is not only empowering but also vision for efficient 21st century healthcare delivery.

In conclusion, it must be reiterated that these standards cannot be considered either in isolation or as "etched in stone for all eternity". These will need to undergo periodic review and update as necessary. Hence, this document must be a "living document".

Standards at a Glance

This section is provided for quick reference. Details are provided in the subsequent sections. N.B., this is a tentative list only.

S. No.	Type	Standard Name	Intended Purpose
1	Identification & Demographics	ISO/TS 22220:2011 Health Informatics – Identification of Subjects of Health Care	Basic identity details of patient
2		MDDS – Demographic (Person Identification and Land Region Codification) version 1.1	Complete demographic for interoperability with E-Governance systems
3	Patient Identifiers	UIDAI Aadhaar	Preferable identifier where available
4		Local Identifier	Identifier given within institution / clinic / lab
5		Government Issued Photo Identity Card Number	Identifier in conjunction with local in absence of Aadhaar
6	Architecture Requirements	ISO 18308:2011 Health Informatics – Requirements for an Electronic Health Record Architecture	System architectural requirements
7	Functional Requirements	ISO/HL7 10781:2015 Health Informatics - HL7 Electronic Health Records-System Functional Model Release 2 (EHR FM)	System functional requirements
8	Reference Model and Composition	ISO 13940 Health informatics - System of Concepts to Support Continuity of Care	Concepts for care, actors, activities, processes, etc.
9		ISO 13606 Health informatics - Electronic Health Record Communication (Part 1 through 3)	Information model architecture and communication
10		openEHR Foundation Models Release 1.0.2	Structural definition and composition
11	Terminology	SNOMED Clinical Terms (SNOMED CT)	Primary terminology
12	Coding System	Logical Observation Identifiers Names and Codes (LOINC)	Test, measurement, observations
13		WHO Family of International Classifications (WHO-FIC) including ICD, ICF, ICHI, ICD-O	Classification and reporting

STANDARDS AT A GLANCE

S. No.	Type	Standard Name	Intended Purpose
14	Imaging	Digital Imaging and Communications in Medicine (DICOM) PS3.0-2015	Image, waveform, audio/video
15	Scanned or Captured Records	JPEG lossy (or lossless) with size and resolution not less than 1024px x 768px at 300dpi	Image capture format
16		ISO/IEC 14496 - Coding of Audio-Visual Objects	Audio/Video capture format
17		ISO 19005-2 Document Management - Electronic Document File Format for Long-Term Preservation - Part 2: Use of ISO 32000-1 (PDF/A-2)	Scanned documents format
18	Data Exchange	ANSI/HL7 V2.8.2-2015 HL7 Standard Version 2.8.2 - An Application Protocol for Electronic Data Exchange in Healthcare Environments	Event/Message exchange
19		ASTM/HL7 CCD Release 1 (basis standard ISO/HL7 27932:2009)	Summary Records exchange
20		ISO 13606-5:2010 Health informatics - Electronic Health Record Communication - Part 5: Interface Specification	EHR archetypes exchange [Also, refer to openEHR Service Model specification]
21		DICOM PS3.0-2015 (using DIMSE services & Part-10 media/files)	Imaging/Waveform Exchange
22	Other Relevant Standards	Bureau of Indian Standards and its MHD-17 Committee	Standards Development Organizations (SDOs)
23		ISO TC 215 set of standards	
24		IEEE/NEMA/CE standards for physical systems and interfaces	
25	Discharge/ Treatment Summary	Medical Council of India (MCI) under regulation 3.1 of Ethics	Composition as prescribed
26	E-Prescription	Pharmacy Practice Regulations, 2015 Notification No. 14-148/ 2012- PCI as specified by Pharmacy Council of India	Composition as prescribed
27	Personal Healthcare and medical Device Interface	IEEE 11073 health informatics standards and related ISO standards for medical devices	Device interfacing
28	Data Privacy and Security	ISO/TS 14441:2013 Health Informatics – Security & Privacy Requirements of EHR Systems for Use in Conformity Assessment	Basis security and privacy requirements

STANDARDS AT A GLANCE

S. No.	Type	Standard Name	Intended Purpose
29	Information Security Management	ISO/DIS 27799 Health informatics - Information Security Management in Health using ISO/IEC 27002	Overall information security management
30	Privilege Management and Access Control	ISO 22600:2014 Health informatics - Privilege Management and Access Control (Part 1 through 3)	Access control
31	Audit Trail and Logs	ISO 27789:2013 Health informatics - Audit trails for Electronic Health Records	Audit trail
32	Data Integrity	Secure Hash Algorithm (SHA) used must be SHA-256 or higher	Data Hashing
33	Data Encryption	Minimum 256-bits key length	Encryption key
34		HTTPS, SSL v3.0, and TLS v1.2	Encrypted connection
35	Digital Certificate	ISO 17090 Health informatics - Public Key Infrastructure (Part 1 through 5)	Digital certificates use and management

***Note**: Where year of publication or version of standard (or its parts) is not provided explicitly, the latest published version of standard (or its parts) available from standard body as on the date of notification / circulation of this recommendation is to be used.*

STANDARDS AT A GLANCE

List of Supporting / Complimenting Standards

The following list is indicative and representative and not comprehensive or definitive. These standards are advised to be used where applicable and as required.

S. No.	Standard	Description
1	ISO 12967:2009	Health Informatics - Service Architecture (Parts 1 - 3)
2	ISO 13972:2015	Health Informatics - Detailed Clinical Models, Characteristics and Processes
3	ISO 20301:2014	Health Informatics - Health Cards - General Characteristics
4	ISO 21090:2011	Health Informatics - Harmonized Data Types for Information Interchange
5	ISO 8601:2004	Data elements and Interchange Formats - Information Interchange - Representation of Dates and Times
6	ISO 13119:2012	Health Informatics - Clinical Knowledge Resources - Metadata
7	ISO 22857:2013	Health Informatics – Guidelines on Data Protection to Facilitate Trans-Border Flows of Personal Health Data
8	ISO 21549-1:2013	Health Informatics — Patient Healthcard Data — Part 1: General Structure
9	ISO TS 14265:2011	Classification of Purposes for Processing Personal Health Information
10	ISO TS 27527:2010	Health Informatics – Provider Identification

Standards and Interoperability

INTEROPERABILITY STANDARDS

The primary aim of interoperability standards is to ensure syntactic (structural) and semantic (inherent meaning) interoperability of data amongst systems at all times. The need for that cannot be overstated, more so within healthcare information systems whose primary aim is to deliver life-long clinical care at all times so that the person being cared for is able to maintain his/her health.

The set of standards outlined in this document represents an incremental approach to adopting standards, implementation specifications; criteria to enhance the interoperability, functionality, utility, and security of health information technology; and to support its widespread adoption. It is to be kept in mind that these standards need to be flexible and modifiable to adapt to the demographic and resource variance observed in a country like India with its large population with diverse culture that is spread across a large region of varied geographical landscapes – hilly regions, river basins, desert, coast, etc. – many of which are remote and accessible with difficulty.

It is important to recognize that interoperability and standardization can occur at many different levels. To achieve interoperability, information models would need to be harmonized into a consistent representation.

In other cases, organizations may use the same information model, but use different vocabularies or code sets (for example, SNOMED CT or ICD10) within those information models. To achieve interoperability at this level, standardizing vocabularies, or mapping between different vocabularies may be necessary. For some levels, (such as the network transport protocol), an industry standard that is widely used (e.g. TCP/IP – Transmission Control Protocol and Internet Protocol) will likely be the most appropriate. Ultimately, to achieve true interoperability, it is anticipated that multiple layers – network transportation protocols, data and services descriptions, information models, and vocabularies and code sets – will need to be standardized and/or harmonized to produce an inclusive, consistent representation of the interoperability requirements.

It is further anticipated that using a harmonization process will integrate different representations of health care information into a consistent representation and maintain and update that consistent representation over time. For an information model, this process could include merging related concepts, adding new concepts, and mapping concepts from one representation of health care information to another. The need to support standardization of data and services descriptions and vocabularies and codes sets is appropriately addressed.

It is also recognized that a sustainable and incremental approach to the adoption of standards will require processes for harmonizing both current and future standards. This will allow the incremental updating of the initial set of standards, implementation specifications, and certification criteria and provide a framework to maintain them. The decision to adopt such updates will be informed and guided by recommendations from an appropriate authority such as the proposed National eHealth Authority (NeHA), Ministry of Health & Family Welfare or expert groups.

STANDARDS AND INTEROPERABILITY

GOALS

The goals of standards in electronic health record systems are:

- Promote interoperability and where necessary be specific about certain content exchange and vocabulary standards to establish a path forward toward semantic interoperability
- Support the evolution and timely maintenance of adopted standards
- Promote technical innovation using adopted standards
- Encourage participation and adoption by all vendors and stakeholders
- Keep implementation costs as low as reasonably possible
- Consider best practices, experiences, policies and frameworks
- To the extent possible, adopt standards that are modular and not interdependent.

Health Record IT Standards

IDENTIFICATION AND DEMOGRAPHIC INFORMATION OF PATIENT

Demographic information including a unique identifier is necessary in a health record system in order to capture identifying information as well as identifiers for linking other medical artifacts logically as well as physically. All health record systems must therefore adhere to the following standards for capturing information related to patient demography and identifiers:

1. ISO/TS 22220:2011 Health Informatics – Identification of Subjects of Health Care
2. MDDS – Demographic (Person Identification and Land Region Codification) version 1.1 from E-Governance Standards, Government of India

Implementation Guideline: Implementers must insure that health record application is able to capture all data fields as provided in the above two standards for completeness. It should also ensure that the system is able to interoperate (receive/import/send/export) all demographics information as provided in above two standards as per demand, i.e. when requested for demographics data in MDDS compliant format it should generate artefacts (file, message, etc.) as per that standard. Where codes related to location, authority, type of organization etc. are required, they should be taken from the MDDS-Demographic Standard.

A health record system must have provision to include patient identifiers of following types:

1. UIDAI Aadhaar Number (preferred where available)
2. Both of following in case Aadhaar is not available:
   2.1 Local Identifier (as per scheme used by HSP)
   2.2 Any Central or State Government issued Photo Identity Card Number

Implementation Guidelines:

1. Implementers must ensure that the Aadhaar number, where that is available, be used as the preferred identifier to serve as the unique health identifier. In case the Aadhaar number is not available, the system should allow a user to insert more than one (minimum two) identifiers for each patient along with its scope and provider (as given in above mentioned patient demography standards) in the system. In situations where identity of patient cannot be obtained or ascertained, temporary identifiers may be used (as per scheme used by HSP) and later confirmed identifiers may be inserted (while making earlier ones as inactive).
2. *Identification of Patient across EHR systems*: Due to lack of mandate for use of Aadhaar or any such alternative(s) national unique identifier, it is difficult to match patient records when exchanging them between two EHR systems. This may lead to situations where different combinations of local identifier and photo identity card numbers of the same person are used at different locations and/or in solutions.

Thus, a single person may get to have different identities under which his/her records are captured. A conflict resolution process may be required to help resolve such cases. At this time, there is no direct solution available other than to use smart (possibly heuristic) algorithms to attempt to match records without or with intervention/confirmation of a human supervisor. Such an algorithm may use name (phonetic or spelling), address (full or parts), date of birth / age, gender, or other such matching details to mark incoming or searched records as possible or exact match before amalgamation or subsequent use. ISV may additionally need to provide the ability to merge/demerge patients to support this process within their solutions.

ARCHITECTURE REQUIREMENTS AND FUNCTIONAL SPECIFICATIONS

A health record system must meet architectural requirements and functional specifications to remain faithful to the needs of service delivery, be clinically valid and reliable, meet legal and ethical requirements, and support good medical practices. Therefore, a health record system must conform to the following standards:

1. ISO 18308:2011 Health Informatics – Requirements for an Electronic Health Record Architecture
2. ISO/HL7 10781:2015 Health Informatics - HL7 Electronic Health Records-System Functional Model Release 2 (EHR FM)

Implementation Guideline: Above two standards, despite being extensive, are not full set of specifications and requirements to be met by a health record system or its many variants (PHR, etc.) or all possible use cases. The above mentioned standards are to be used as minimum set to be used within the scope of implementation as per relevance to the system being developed / deployed.

LOGICAL INFORMATION REFERENCE MODEL AND STRUCTURAL COMPOSITION

A health record system must accumulate observable data and information for all clinically relevant events and encounters. For this purpose, it is important to have common semantic and syntactic logical information model and structural composition for captured artefacts. Unless the data being captured is standardized, its communication and understanding may not be same across systems. Therefore, a health record system must conform to the following standards:

1. ISO 13940 Health Informatics - System of Concepts to Support Continuity of Care
2. ISO 13606 Health Informatics - Electronic Health Record Communication (Part 1 though3)
3. openEHR Foundation Models Release 1.0.2
    3.1 Required Model Specifications: Base Model, Reference Model, Archetype Model
    3.2 Optional Model Specifications: Service Model, Querying, Clinical Decision Support

Implementation Guideline: The ISO 13940 (also known as CEN ContSys) is to be generally used for purpose of modelling and describing concept system and organize information objects. While ISO 13606 set of

standards are basic reference model and related specifications, openEHR provides ISO 18308 conformant platform-independent implementation harmonized with ISO 13606 standard. Implementers are free to design internal structures, databases, and user interfaces as per the requirements and technology platforms but structural composition for clinical data/information artefact must be logically similar to Reference Model given in above standards. openEHR Operational Templates (OPT) adopted by an implementation, are to be public and free in required format for other implementers to ensure interoperability among them.

MEDICAL TERMINOLOGY AND CODING STANDARDS

In order to have semantic interoperability between different health record systems, it is necessary to follow a common terminology and coding system standards to express unambiguous meaning of data captured, stored, transmitted, and analyzed. It is also important to have these terminologies and codes in computer process-able format to aid automation and ensure that data is in an analyzable state at all times. Therefore, a health record system must conform to the following standards:

1. Primary Terminology: IHTSDO - SNOMED Clinical Terms (SNOMED CT)

Implementation Guideline: A health record system must use SNOMED CT as the primary internal encoding system for all clinically relevant, including dental, nursing, substance/drugs, information. IHTSDO SNOMED CT code shall also be used while communicating clinical information to other health record systems. SNOMED CT concept codes (as pre-coordinated or as post-coordinated expressions) are to be used for all hierarchies covered under the standard unless otherwise provided in this document. It shall also be the coding system that must be used internally in other information storage and communication standards such as openEHR archetypes, HL7, DICOM, etc. IHTSDO releases SNOMED CT twice annually.

2. Test, Measurement and Observation Codes: Regenstrief Institute - Logical Observation Identifiers Names and Codes (LOINC)

Implementation Guideline: LOINC coding is to be used for processing results and reports with Laboratory and Imaging Information Systems. N.B.: SNOMED CT to LOINC coding interchange map is available from IHTSDO and Regenstrief Institute.

3. Classification Codes: WHO Family of International Classifications (WHO-FIC)
    - 3.1 WHO ICD-10: International Classification of Diseases (ICD) and its derivative classifications
    - 3.2 WHO ICF: International Classification of Functioning, Disability and Health (ICF)
    - 3.3 International Classification of Health Interventions (ICHI)
    - 3.4 International Classification of Diseases for Oncology (ICD-O)

Implementation Guideline: WHO FIC codes are primarily used for aggregated information and statistical/epidemiological analysis for public health purposes derived from health records that contain patient care related information as well as information that is crucial for management, health financing and

general health system administration. While SNOMED CT is to be used by health record systems for terminology, generated classification-based reports may require the use of WHO FIC codes. Classification based reporting, for statistical or regulatory purposes, may continue to use WHO FIC codes as mandated by the health regulatory, intelligence, and various research bodies. N.B.: SNOMED CT to ICD-10 coding interchange map is available from IHTSDO and WHO.

DATA STANDARDS FOR IMAGE, MULTIMEDIA, WAVEFORM, DOCUMENT

A health record system stores data records and files of various types in support of clinical functions. These data elements serve the purpose of documentary records of various diagnostic and prescriptive data or information generated. Therefore, a health record system must conform to the following standards for such data:

1. NEMA Digital Imaging and Communications in Medicine (DICOM) PS3.0-2015

Implementation Guideline: NEMA DICOM PS3.0-2015 is a comprehensive standard for handling and managing image (series or single), waveforms (such as those in ECG/EEG), audio (such as those in digital-stethoscope) and video (such as those in endoscope, ultrasound) data in medicine. A health record implementation is required to implement relevant DICOM Information Object Definitions (IODs) for supported data types in Part-10 compliant files. Where required and relevant, other features of standard such as services, display, print, and workflow may be implemented.

2. Scanned or Captured Records:

    2.1 Image: JPEG lossy (or lossless) with size and resolution not less than 1024px x 768px at 300dpi

    2.2 Audio/Video: ISO/IEC 14496 - Coding of Audio-Visual Objects

    2.3 Scanned Documents: ISO 19005-2 Document Management - Electronic Document File Format for Long-Term Preservation - Part 2: Use of ISO 32000-1 (PDF/A-2) (ref: Best Practices and Guidelines for Production of Preservable e-Records Ver1.0 from DeitY, Ministry of Comm. & IT, Govt. of India)

Implementation Guideline: The above mentioned standards are to be used for documentary data (scan for prescription, summaries, etc.) and data captured through traditionally non-DICOM compliant sources like picto-micrographs, pathological photographs, photographs of intramural and extramural lesions, etc. All data formats that can be converted into relevant DICOM format should be, as relevant, converted and communicated as secondary captured DICOM format. It may be noted that while no maximum image resolution has been prescribed, a sufficiently acceptable limit may be used to avoid unnecessarily large file that do not aid in correspondingly better diagnosis or analysis.

DATA EXCHANGE STANDARDS

A health record system has to operate in a larger ecosystem of other components with which it must share or communicate data in order to capture and provide as comprehensible medical information as is practical. A health record system must therefore conform to the following standards:

1. Event/Message Exchange: ANSI/HL7 V2.8.2-2015 HL7 Standard Version 2.8.2 - An Application Protocol for Electronic Data Exchange in Healthcare Environments
2. Summary Records Exchange: ASTM/HL7 CCD Release 1 (basis standard ISO/HL7 27932:2009)
3. EHR Archetypes: ISO 13606-5:2010 Health informatics - Electronic Health Record Communication - Part 5: Interface Specification [Also, refer to openEHR Service Model specification]
4. Imaging/Waveform Exchange: NEMA DICOM PS3.0-2015 (using DIMSE services& Part-10 media/files)

Implementation Guideline: Implementation of exchange standards is expected to be at least for the scope of data captured or retained by the health record system. To explain further, full implementation of ANSI/HL7 V2.8.2 for each event and message is not required in health record systems but minimum implementation supporting the types of events and messages relevant to the system is required. Similarly, implementation/support of DICOM DIMSE C-Store and/or C-FIND/C-GET service is expected for IODs supported by health record system whereas implementation of WADO could be optional.

OTHER STANDARDS RELEVANT TO HEALTHCARE SYSTEMS

Healthcare record systems need to co-exist within a larger ecosystem with various other systems. It is important for all systems within a healthcare setup to adhere to relevant standards. While standards related to such systems are not within the scope of this document, as a general rule, standards created or ratified by following Standard Development Organizations (SDOs) should be used:

1. Bureau of Indian Standards and its MHD-17 Committee
2. ISO TC 215 set of standards
3. IEEE/NEMA/CE standards for physical systems and interfaces

Implementation Guideline: To help the implementers, an indicative list of such standards is provided in the "Standards at a Glance" section above. BIS approved standards shall be preferred for implementation.

DISCHARGE/TREATMENT SUMMARY FORMAT

Implementers must ensure that the logical information model includes data elements to satisfy requirements of the format for Medical Records as specified by Appendix-3 of Medical Council of India (MCI) Code of Ethics Regulation 2002 (amended up to Feb-2016). The printed reports should meet MCI prescribed format whenever any discharge or treatment summary is prepared.

HEALTH RECORD IT STANDARDS

E-PRESCRIPTION

Pharmacy Council of India (PCI) has, in its recent regulation (Pharmacy Practice Regulations, 2015 Notification No. 14-148/ 2012- PCI), provided the definition of the term under Section 2(j) that the term 'Prescription' includes the term 'electronic direction'. Implementers must therefore ensure that the logical information model includes data elements to satisfy requirements of the format for Medical Prescription as specified by the Pharmacy Council of India. The printed prescription will need to be in the PCI prescribed format whenever any medical prescription meant for drug dispensing is prepared. For the purpose of e-Prescription, implementers must ensure that the electronic version is digitally signed by a registered medical practitioner, and its non-repudiation is ensured at all times. The pharmacists shall be able to print a copy of e-Prescription in the required format along with other relevant digital authentication details.

PERSONAL HEALTHCARE AND MEDICAL DEVICES INTERFACING

Where not covered under relevant data exchange standards, it is recommended that IEEE 11073 health informatics standards and related ISO standards for medical devices be followed as appropriate whenever any personal healthcare/medical device is interfaced with the EMR system for the purpose of clinical data exchange, retrieval, storage, etc.

PRINCIPLES OF DATA CHANGE

The data once entered into a health record system must become immutable. The healthcare provider may have the option to re-insert/append any record in relation to the medical care of the patient as necessary with a complete audit trail of such change maintained by system. Alteration of the previously saved data should not be permitted. No *update* or *update like* command shall be accessible to user or administrator to store a medical record or part thereof. Any record requiring revision should create a new medical record containing the changed/appended/modified data of earlier record. This record shall then be stored and marked as ACTIVE while rendering the previous version(s) of the same record marked INACTIVE. The data will thus be immutable. A strict audit trail shall be maintained of all activities at all times that may be suitably reviewed by an appropriate authority like auditor, legal representatives of the patient, the patient, healthcare provider, privacy officer, court appointed/authorized person, etc.

As-Is Principal:

The data captured through the devices is usually in a certain format whereas the data given by the doctor as file may be in some different format. These data provided / included in the system is to be treated as sacrosanct. The As-Is Principal requires that the data captured in the first instance should be retrievable at any given point of time later in the same format, clarity, size and detail as it was provided in the beginning.

It effectively means that the system is not allowed to make any changes either to the data or its format or its nature at any point other than the creation time for any reason. However, if it is required that the data needs to be altered either to carry some additional information at some later point, like annotation on images, or correction of errors of omission or commission, etc., it must be done on a copy of the original data, keeping the original data intact, and marking the updated version as active while marking the previous version inactive. The modified data will become part of the EHR/EMR.

Informed Format Change:

Whenever, the data, its format or its nature needs to be changed within the system, it must be done with the explicit consent of the doctor / technician / person that is entering or managing the data. This explicit consent can also be taken from a set of preferences already set by the user or the administrator / root of the system. In such preference based consent, there is no need to prompt the user for permission at each insertion point.

Also, in case the system is set to change format or nature of data automatically by setting of preferences, it must be made sure that the rule of conversion is declared in the Standard Operating Procedure (SOP) of site/application.

Guidelines

HARDWARE

- The IT hardware used should meet (and preferably be better than) the optimal requirements specified by the software (to be) used.
- The medical and IT hardware used must meet the relevant applicable specifications from BIS, NEMA, IEEE, ISO, CE, RoHS, EnergyStar, apart from Medical and IT standards for the equipment.
- A backup or data preservation mechanism should be considered. Data capacity should be planned to meet the storage requirement as per the mandated rule/law.
- System redundancy at various levels (disk, power, network, etc.) should be planned to meet the organizational system availability requirement.
- Network and data security should be planned, implemented, and periodically audited. Please see section on Security and Privacy for the various requirements and functions that need to be supported and implemented.
- Hardware should be checked periodically for correctness and completeness of operation expected from them. An appropriate maintenance cycle should be planned and rigorously followed.
- Planned and expected Capacity and Quality requirement of the organization should be met by the hardware used. Periodic updates and upgrades should be carried out to meet the requirements.

NETWORKING AND CONNECTIVITY

- Should be able to harness any telecommunications-related connectivity like the Internet, LAN, WAN, WAP, CDMA, GSM or even Cloud Computing that will permit the various EMRs of an individual to be integrated into a single lifelong electronic health record
- As far as is practical and affordable, the connectivity medium chosen should be reliable and fast enough to sustain a secure data exchange for the period expected for transaction of records and data. The speed of the connectivity medium should be chosen from among available options so as to provide an acceptable user experience and not cause software/system fault due to delays/noise/failure.
- Should be able to ensure that data exchange is performed in a secure manner to ensure data validity and non-repudiability
- The data exchange must further ensure that data integrity is maintained at all times

SOFTWARE STANDARDS

The software for capturing, storing, retrieving, viewing, and analyzing healthcare records should:

- Conform to the specified standards
- Satisfy specified requirements
- Be Interoperable, especially in terms of syntax and semantics of the information being exchanged

- Should be able to ensure user authentication and authorization
- Should be able to support privacy, secrecy and audit trail
- Possess advanced search, merge, and demerge functionality to ensure that duplicates are robustly resolved
- Should be able to support conception-to-current/most recent medical records of a person (as relevant to scope of application)
- Should be able to support digital archiving and retrieval of medical records after the death of a person for the total duration as specified by Government of India from time to time
- Should be able to construct a medical/clinical summary based on available records from the very first visit to current/most recent
- Preferably be able to support rapid data capture-storage-retrieval-display of data

HEALTH RECORD IN MOBILE DEVICES

As people become more mobile and travel becomes more accessible, patients will increasingly expect the healthcare record system to provide essential health information over mobile devices, which will give their treating clinician basic information like, medical condition, drug/allergy information etc. Demographics, insurance info, medications, allergy and alerts, and vital signs are some of the records that are recommended to be provided in at least read-only manner and to the extent relevant for emergency care and quick reference. It is also possible that certain clinical (BP, temperature, glucose count) and lifestyle (steps walked, distance run, sleep duration and quality) related information will additionally be provided by the patient thereby providing vital clues and information on the overall wellbeing of patient.

In the specific regard of design and usability of such applications, "Framework for Mobile Governance 2012" of DeitY, Ministry of Communication & Information Technology, Government of India shall be applicable.

DATA OWNERSHIP OF HEALTH RECORDS

Data Ownership of Health Records

THE ETHICAL, LEGAL, SOCIAL ISSUES (ELSI) GUIDELINES

For the purposes of these recommendations, the term "privacy" shall mean that only those person or person(s) including organizations duly authorized by the patient may view the recorded data or part thereof. The term "security" shall mean that all recorded personally identifiable data will at all times be protected from any unauthorized access, particularly during transport (e.g. from healthcare provider to provider, healthcare provider to patient, etc.). The term "trust" shall mean that person, persons or organizations (doctors, hospitals, and patients) are those who they claim they are.

The following approaches are to be adopted wherever applicable to address the aspects that the terms mentioned above refer to:

- Privacy would refer to authorization by the owner of the data (the patient)
- Security would have as components both public and private key encryption; the encryption techniques used in transit and at rest need to be through different methodologies.
- Trust would be accepted whenever a trusted third party confirms identity

PROTECTED HEALTH INFORMATION

Protected Health Information (PHI) would refer to any individually identifiable information whether oral or recorded in any form or medium that (1) is created, or received by a stakeholder; and (2) relates to past, present, or future physical or mental health conditions of an individual; the provision of health care to the individual; or past, present, or future payment for health care to an individual.

Electronic Protected Health Information (ePHI) would refer to any protected health information (PHI) that is created, stored, transmitted, or received electronically. Electronic protected health information includes any medium used to store, transmit, or receive PHI electronically.

As per the Information Technology Act 2000, Data Privacy Rules, refers to 'sensitive personal data or information' (SPI) as the subject of protection, but also refers, with respect to certain obligations, to 'personal information' (PI). Sensitive personal information is defined as a subset of personal information. Followings are Sensitive personal information that relates to:

1. Passwords
2. Financial information such as bank account or credit card or debit card or other payment instrument details
3. Physical, psychological and mental health condition
4. Sexual orientation
5. Medical records and history
6. Biometric information

7. Any detail relating to (1) – (6) above received by the body corporate for provision of services
8. Any information relating to (1) – (7) that is received, stored or processed by the body corporate under a lawful contract or otherwise

DATA OWNERSHIP

- The physical or electronic records, which are generated by the healthcare provider, are held in trust by them on behalf of the patient
- The contained data in record which are the protected health information of the patient is owned by the patient herself.
- The medium of storage or transmission of such electronic medical record will be owned by the healthcare provider.
- The "sensitive personal information (SPI) and personal information (PI)" of the patient is owned by the patient herself. Refer to IT Act 2000 for the definition of SPI and PI.

DATA ACCESS AND CONFIDENTIALITY

- Regulations are to be enforced to ensure confidentiality of the recorded patient/medical data and the patient should have a control over this.
- Patients will have the sufficient privileges to inspect and view their medical records without any time limit. Patient's privileges to amend data shall be limited to correction of errors in the recorded patient/medical details. This shall need to be performed through a recorded request made to the healthcare provider within a period of 30 days from the date of discharge in all inpatient care settings or 30 days from the date of clinical encounter in outpatient care settings. An audit of all such changes shall be strictly maintained. Both the request and audit trail records shall be maintained within the system.
- Patients will have the privileges to restrict access to and disclosure of individually identifiable health information and need to provide explicit consent, which will be audited, to allow access and/or disclosures.
- All recorded data will be available to care providers on an 'as required on demand' basis

DISCLOSURE OF PROTECTED / SENSITIVE INFORMATION

- For use in treatment, payments and other healthcare operations: In all such cases, a general consent must be taken from the patient or next of kin, etc. as defined by applicable laws by MCI.
- Fair use for non-routine and most non-health care purposes: A specific consent must be taken from the patient; format as defined by MCI.
- For certain specified national priority activities, including notifiable/communicable diseases, the health information may be disclosed to appropriate authority as mandated by law without the patient's prior authorization
- Instances where use and disclosure without individual authorization will be possible are as follows:
- Complete record with all identifiers in an "as-is" state, on production of court order

DATA OWNERSHIP OF HEALTH RECORDS

- Totally anonymized data, where the anonymization process involves the complete removal of all information that allows the identification of the patient. (List of such personally identifiable information is provided below)

RESPONSIBILITIES OF A HEALTHCARE PROVIDER

- Protect and secure the stored health information, as per the guidelines specified in this document
- While providing patient information, remove patient identifying information (as provided in the list below), if it is not necessary to be provided
- Will ensure that there are appropriate means of informing the patient of policies relating to her/his rights to health record privacy
- Document all its privacy policies and ensure that they are implemented and followed. This will include:
- Develop internal privacy policies
- Ensure implementation of privacy policies, audit and quality assurance
- Provide privacy training to all its staff

PRIVILEGES OF PATIENT OR PERSONAL REPRESENTATIVE

Patient will have the privilege to carry out the activities detailed below, personally, or through appointed representative.

- Patients can demand from a healthcare provider for a copy of its medical records held by that healthcare provider, which should be provided within 30 days of receipt of communication of request.
- Patients can demand from a healthcare provider that stores/maintains his/her medical records, to withhold, temporarily or permanently, specific information that he/she does not want disclosed to other organizations or individuals.
- Patient can demand information from a healthcare provider on the details of disclosures performed on the patient's medical records for any reason whatsoever. When demanded, following details are to be provided for each instance of disclosure:
    - Date of the disclosure
    - Name and address of the entity or person who received the information
    - Brief description of the medical information disclosed
    - Brief summary of the purpose of the disclosure

DENIAL OF INFORMATION

Healthcare provider will be able to deny information to a patient or representative or third party, in contravention of normal regulations, if in the opinion of a licensed healthcare professional the release of information would endanger the life or safety of the patients and others. This will include but not be limited to as follows:

- Information obtained from an anonymous source under a promise of confidentiality.
- Psychotherapy notes.
- Information compiled for civil, criminal or administrative action.

ELECTRONIC MEDICAL RECORDS PRESERVATION

Preservation of medical records assume significant importance in view of the fact that an electronic health record of a person is an aggregation of all electronic medical records of the person from the very first entry till date. Hence, all records must compulsorily be preserved and not destroyed during the life-time of the person, ever.

Upon the demise of the patient where there are no court cases pending, the records can be removed from active status and turned to inactive status. HSPs are free to decide when to make a record inactive, however, it is preferable to follow the "three (3) year rule" where all records of a deceased are made inactive three (3) years after death.

It is however preferred and HSPs are strongly encouraged to ensure that the records are never be destroyed or removed permanently. The health of the blood relatives and natural descendants of the person can be strongly influenced by the health of the person and on-demand access to these may prove to be hugely useful in the maintenance of the health of the relations.

Furthermore, analysis of health data of all persons is expected to greatly benefit in the understanding of health, disease processes and the amelioration thereof.

With rapid decline in costs of data archiving coupled with the ability to store increasing amounts of data that may be readily accessible, continued maintenance of such data is not expected to lead to any major impact on the overall system maintenance and use.

PATIENT IDENTIFYING INFORMATION

Data are "individually identifiable" if they include any of the under mentioned identifiers for an individual or for the individual's employer or family member, or if the provider or researcher is aware that the information could be used, either alone or in combination with other information, to identify an individual. These identifiers are as follows:

- Name
- Address (all geographic subdivisions smaller than street address, and PIN code)
- All elements (except years) of dates related to an individual (including date of birth, date of death, etc.)
- Telephone, cell (mobile) phone and/or Fax numbers
- Email address
- Bank Account and/or Credit Card Number
- Medical record number
- Health plan beneficiary number

- Certificate/license number
- Any vehicle or other any other device identifier or serial numbers
- PAN number
- Passport number
- AADHAAR card
- Voter ID card
- Fingerprints/Biometrics
- Voice recordings that are non-clinical in nature
- Photographic images and that possibly can individually identify the person
- Any other unique identifying number, characteristic, or code

APPLICABLE LEGISLATION

The existing Indian laws including IT Act 2000 and their amendments from time to time would prevail. (http://deity.gov.in/content/information-technology-act-2000).

Data Privacy and Security

SECURITY OF ELECTRONIC HEALTH INFORMATION:

The Privacy Standards and the Security Standards are necessarily linked. Any health record system requires safeguards to ensure that the data is available when needed and that information is not used, disclosed, accessed, altered, or deleted inappropriately while being stored or retrieved or transmitted. The Security Standards work together with the Privacy Standards to establish appropriate controls and protections. Health sector entities that are required to comply with the Privacy Standards also must comply with the Security Standards.

Organizations must consider several factors when adopting security measures. How a healthcare provider satisfies the security requirements and which technology it decides to use are business decisions left to the individual organizations. In deciding what security measures to adopt, an organization must consider its size, complexity, and capabilities; it's technical infrastructure, hardware, and software security capabilities; the cost of particular security measures; and the probability and degree of the potential risks to the ePHI it stores, retrieves and transmits.

PURPOSE OF THE SECURITY STANDARDS

The security standards require healthcare providers to implement reasonable and appropriate *administrative*, *physical*, and *technical* safeguards to:

- ensure the confidentiality, integrity, and availability of all the e-PHI they create, transmit, receive, or maintain
- protect against reasonably anticipated threats or hazards to the security or integrity of their e-PHI
- protect against uses or disclosures of the e-PHI that are not required or permitted under the Privacy Standards
- ensure their workforce will comply with their security policies and procedures

SECURUTY TECHNICAL STANDARDS

To protect the ePHI handles by a healthcare provider, the provider must implement technical safeguards as part of its security plan. Technical safeguards refer to using technology to protect ePHI by controlling access to it. Therefore, they must address the following standards focusing on the following functionalities. It is worth noting that they will need to use an EHR/EMR solution that is able to successfully and robustly demonstrate the possession and working of these functionalities.

The basic requirements for security and privacy are provided in following standard:

1. ISO/TS 14441:2013 Health Informatics – Security & Privacy Requirements of EHR Systems for Use in Conformity Assessment

DATA PRIVACY AND SECURITY

Authentication:

- Locally within the system the fact that a person or entity seeking access to electronic health information is indeed the one as claimed and is also authorized to access such information must be verifiable.
- Across the network, however extensive it might be, the fact that a person or entity seeking access to electronic health information across a network is the one claimed and is authorized to access such information in accordance with the standard specified in this document must be verifiable.

Automatic log-off: An electronic session after a predetermined time of inactivity must be forcibly terminated. To log in back, the user will have to initiate a new log in session. However, for the sake of ergonomics, it is recommended that the unsaved state of the system at the time of automatic log-off be saved and presented back to the user for further action. This should be a user-specific feature.

The advisory standard for overall information security management in health is:

2. ISO 27799 Health informatics - Information Security Management in Health using ISO/IEC 27002

Implementation Guideline: The ISO 27799 is provided as a basic advisory standard for security management. Other security management and standard / practices / guidelines given by Law (such as IT Act 2000 and amendments) or regulatory / statutory / certification bodies (such as National Accreditation Board for Hospitals & Health care Providers (NABH)) should be taken in consideration when designing and/or implementing health record system.

Access control: The solution must assign a unique name and/or number for identifying and tracking user identity and establish controls that permit only authorized users to access electronic health information. In cases of emergency where access controls need to be suspended in order to save a live, authorized users (who are authorized for emergency situations) will be permitted to have unfettered access electronic health information for the duration of the emergency with the access remaining in force during the validity of the emergency situation.

Access Privileges: Ideally only clinical care providers should have access rights to a person's clinical records. However, different institutional care providers have widely varying access privileges specified that are institution-specific. No country-wide standards can be specified for this at least at this point in time.

For privilege management and access control, following standards may be used:

3. ISO 22600:2014 Health informatics - Privilege Management and Access Control (Part 1 through 3)

Implementation Guideline: The ISO 22600 set of standards is provided as an advisory standard for policy based access control. For the purpose of privilege management, rule / policy based access is expected to give better control and flexibility in defining and enforcing access control. Access control mechanisms such

as Role Based, Policy Based, or singular user (applicable in case of mobile based PHR) are acceptable as long as conformant to applicable data security law(s) and rules as well as policy of the organization where implemented.

Audit log:

- All actions related to electronic health information in accordance with the standard specified in this document including viewing should be recorded.
- All actions based on user-defined events must be recorded.
- All or a specified set of recorded audit information, upon request or at a set period of time, must be electronically displayed or printed for user/administrative review.
- All actions related to electronic health information must be recorded with the date, time, record identification, and user identification whenever any electronic health information is created, modified (non-clinical data only), deleted (stale and non-clinical data only), or printed; and an indication of which action(s) took place must also be recorded.
- A cross-enterprise secure transaction that contains sufficient identity information such that the receiver can make access control decisions and produce detailed and accurate security audit trails should be preferably used within the system.

The advisory standard for audit trail / log in health record system is:

4. ISO 27789:2013 Health informatics - Audit Trails for Electronic Health Records

Integrity:

- During data transit the fact that the electronic health information has not been altered in transit in accordance with the standard specified in this document must be verifiable.
- Detection of events – all alterations and deletions of electronic health information and audit logs, in accordance with the standard specified in this document must be detected.
- Appropriate verification that electronic health information has not been altered in transit shall be possible at any point in time. A secure hashing algorithm must be used to verify that electronic health information has not been altered in transit and it is recommended that the Secure Hash Algorithm (SHA) used must be SHA-256 or higher.

Encryption:

- Generally, all electronic health information must be encrypted and decrypted as necessary according to organization defined preferences in accordance with the best available encryption key strength (minimum 256-bits key).
- During data exchange all electronic health information must be suitably encrypted and decrypted when exchanged in accordance with an encrypted and integrity protected link.

- Secure Transmission standards and mechanisms must be used to allow access to health information as well as transmit data from one application / site to another. For this purpose HTTPS, SSL v3.0, and TLS v1.2 standards should be used. Please refer to relevant IETF, IEEE, ISO, and FIPS standards for same.

Digital Certificates:

Use of Digital Certificates for identification and digital signing is recommended in health record system. Health record system must use following standard where digital certificates are used:

5. ISO 17090 Health informatics - Public Key Infrastructure (Part 1 through 5)

ADMINISTRATIVE SAFEGUARDS STANDARDS

The Administrative Safeguards require healthcare providers to develop and implement a security management process that includes policies and procedures that address the full range of their security vulnerabilities. Being administrative in nature, these need to be internally designed and developed as standard operating procedure (SOP) that must be published for all users to see and adhere to. Conformance to adherence may be delegated to the Privacy Officer detailed in the Data Ownership chapter above. To comply with the Administrative Safeguards, a healthcare provider must implement the following standards.

- The security management process standard, to prevent security violations;
- Assigned security responsibility, to identify a security officer;
- Workforce security, to determine e-PHI user access privileges;
- Information access management, to authorize access to e-PHI;
- Security awareness training, to train staff members in security awareness;
- Security incident procedures, to handle security incidents;
- Contingency plan, to protect e-PHI during an unexpected event; and
- Evaluation, to evaluate an organization's security safeguards.

PHYSICAL SAFEGUARDS STANDARDS

Physical safeguards are security measures to protect a healthcare provider's electronic information systems, related equipment, and the buildings housing the systems from natural and environmental hazards, and unauthorized intrusion. Healthcare providers must fulfill the following four standards. However, since most of the implementation specifications in this category are addressable, healthcare providers have flexibility in determining how to comply with the requirements as long as these are internally designed and developed as per the relevant SOP and published for all users to see and adhere to. Conformance to adherence may be delegated to the Privacy Officer detailed in the Data Ownership chapter above.

The required physical standards are:

- The facility access control standard, to limit actual physical access to electronic information systems and the facilities where they're located;

- The workstation use standard, to control the physical attributes of a specific workstation or group of workstations, to maximize security;
- The workstation security standard, to implement physical safeguards to deter the unauthorized access of a workstation; and
- The device and media controls standard, to control the movement of any electronic media containing ePHI from, to or within the facility.

GLOSSARY

Glossary

The various terms, including acronyms, are explained from a conceptual point and may not be the formal definitions.

ADSL (Asymmetric Digital Subscriber Line): A type of DSL that uses copper telephone lines to transmit data faster than a traditional modem. ADSL only works within short distances because it uses high frequencies with short signals.

Allergy List: This is a list of all the patient's allergies.

Allopathic, Allopathy: Defined as relating to or being a system of medicine that aims to combat disease by using remedies (as drugs or surgery) which produce effects that are different from or incompatible with those of the disease being treated

Ambulatory care: Any medical care delivered on an outpatient basis.

ANM: Auxiliary Nurse Midwife

Archetype: Basically an information model, it is a computable expression of a domain content model in the form of structured constraint statements, based on a reference (information) model. Within the openEHR paradigm, archetypes are based on the openEHR reference model. Archetypes are all expressed in the same formalism. In general, they are defined for wide re-use, however, they can be specialized to include local particularities. They can accommodate any number of natural languages and terminologies.

Artefact: An object made by a human being, typically one of cultural or historical interest. In healthcare IT context, an artefact is any item such as a document, file or drawing, etc. that is generated for use as a reference material or inside a system.

ASHA: Accredited Social Health Activist is usually a literate 25 – 45 year old married/ widowed/ divorced lady selected from the village itself and accountable to it and trained to work as an interface between the community and the public health system. This is position is one of the key components of the National Rural Health Mission aimed at providing every village in the country with a trained female community health activist

ATC: Anatomical Therapeutic Chemical Classification System, controlled by the WHO Collaborating Centre for Drug Statistics Methodology (WHOCC), is used for drug classification.

Authentication: The verification of the identity of a person or process.

Authorization: Any document designating any permission. Authorization or waiver of authorization for the use or disclosure of identifiable health information for research (among other activities) is required. The authorization must indicate if the health information used or disclosed is existing information and/or new information that will be created. The authorization form may be combined with the informed consent form, so that a patient need sign only one form. An authorization must include the following specific elements: a

description of what information will be used and disclosed and for what purposes; a description of any information that will not be disclosed, if applicable; a list of who will disclose the information and to whom it will be disclosed; an expiration date for the disclosure; a statement that the authorization can be revoked; a statement that disclosed information may be re-disclosed and no longer protected; a statement that if the individual does not provide an authorization, she/he may not be able to receive the intended treatment; the subject's signature and date.

AYUSH: Ayurveda, Yoga, Unani, Siddha and Homeopathy. Falls under the broad category of Indian Systems of Medicines and Homoeopathy (ISM&H) governed by Ministry of Health and Family Welfare, Government of India

[C]

CCD (Continuity of Care Document): A joint effort of HL7 International and ASTM. CCD fosters interoperability of clinical data by allowing physicians to send electronic medical information to other providers without loss of meaning and enabling improvement of patient care. CCD is an implementation guide for sharing Continuity of Care Record (CCR) patient summary data using the HL7 Version 3 Clinical Document Architecture (CDA), Release 2. It establishes a rich set of templates representing the typical sections of a summary record, and these same templates for vital signs, family history, plan of care, and so on can then be used for establishing interoperability across a wide range of clinical use cases.

CDT: Common Dental Terminology

Chain of Trust Agreement: A contract needed to extend the responsibility to protect health care data across a series of sub-contractual relationships.

Chief Complaint (CC), Reason for Consultation (RFC), Reason of Visit (ROV): for recording a patient's disease symptoms.

Client/Server Architecture: An information-transmission arrangement, in which a client program sends a request to a server. When the server receives the request, it disconnects from the client and processes the request. When the request is processed, the server reconnects to the client program and the information is transferred to the client. This usually implies that the server is located on site as opposed to the ASP (Application Server Provider) architecture.

Clinical Care Provider: Personnel or entities directly related to providing clinical care to patient.

Clinical Data Repository (CDR): A real-time database that consolidates data from a variety of clinical sources to present a unified view of a single patient. It is optimized to allow clinicians to retrieve data for a single patient rather than to identify a population of patients with common characteristics or to facilitate the management of a specific clinical department.

Clinical Decision Support System (CDSS): A clinical decision support system (CDSS) is software designed to aid clinicians in decision making by matching individual patient characteristics to computerized knowledge bases for the purpose of generating patient-specific assessments or recommendations.

GLOSSARY

Clinical Establishment: Clinical establishment means (1) a hospital, maternity home, nursing home, dispensary, clinic, sanatorium or an institution by whatever name called that offers services, facilities requiring diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognized system of medicine established and administered or maintained by any person or body of persons, whether incorporated or not; or (2) a place established as an independent entity or part of an establishment referred to above, in connection with the diagnosis or treatment of diseases where pathological, bacteriological, genetic, radiological, chemical, biological investigations or other diagnostic or investigative services with the aid of laboratory or other medical equipment, are usually carried on, established and administered or maintained by any person or body of persons, whether incorporated or not. (Clinical Establishment Act – CEA 2010)

Clinical Guidelines (Protocols): Clinical guidelines are recommendations based on the latest available evidence for the appropriate treatment and care of a patient's condition.

Clinical Messaging: Communication of clinical information within the electronic medical record to other healthcare personnel.

Coded Data: Data are separated from personal identifiers through use of a code. As long as a link exists, data are considered indirectly identifiable and not anonymous or anonymized.

Code Set: Any set of codes used to encode data elements, such as tables of terms, medical concepts, medical diagnostic codes, or medical procedure codes. This includes both the codes and their descriptions.

Coding: A mechanism for identifying and defining physicians' and hospitals' services. Coding provides universal definition and recognition of diagnoses, procedures and level of care. Coders usually work in medical records departments and coding is a function of billing. Medicare fraud investigators look closely at the medical record documentation, which supports codes and looks for consistency. Lack of consistency of documentation can earmark a record as "up-coded" which is considered fraud. A national certification exists for coding professionals and many compliance programs are raising standards of quality for their coding procedures.

Computer-Based Patient Record (CPR): A term for the process of replacing the traditional paper-based chart through automated electronic means; generally includes the collection of patient-specific information from various supplemental treatment systems, i.e., a day program and a personal care provider; its display in graphical format; and its storage for individual and aggregate purposes. CPR is also called "digital medical record" or "electronic medical record".

Computerized Patient Record (CPR): Also known as an EMR or EHR.A patient's past, present, and future clinical data stored in a server.

Computerized Physician Order Entry (CPOE): A system for physicians to electronically order labs, imaging and prescriptions

CPT (Current Procedural Terminology) Code: A recognizable five-digit number used to represent a service provided by a healthcare provider. It is a manual that assigns five digit codes to medical services and procedures to standardize claims processing and data analysis. The coding system for physicians' services developed by the CPT Editorial Panel of the American Medical Association.

[D]

Data Content: All the data elements and code sets inherent to a transaction, and not related to the format of the transaction.

Data: This is factual information (as measurements or statistics) used as a basis for reasoning, discussion, or calculation. It additionally points to the information output by a sensing device or organ that includes both useful and irrelevant or redundant information and must be processed to be meaningful.

Database Management System (DBMS): The separation of data from the computer application that allows entry or editing of data.

DICOM (Digital Imaging and Communications in Medicine): Digital Imaging and Communications in Medicine (DICOM) is a standard to define the connectivity and communication between medical imaging devices.

Disease Management: A type of product or service now being offered by many large pharmaceutical companies to get them into broader healthcare services. Bundles use of prescription drugs with physician and allied professionals, linked to large databases created by the pharmaceutical companies, to treat people with specific diseases. The claim is that this type of service provides higher quality of care at more reasonable price than alternative, presumably more fragmented, care. The development of such products by hugely capitalized companies should be the entire indicator necessary to convince a provider of how the healthcare market is changing. Competition is coming from every direction—other providers of all types, payers, employers who are developing their own in-house service systems, the drug companies.

Document Imaging: Is a process of converting paper documents into an electronic format usually through a scanning process.

Document Management: The Document Manager allows the medical institution to store vital patient documents such as X-Ray's, Paper Reports, and Lab Reports etc.

Documentation: The process of recording information.

DOHAD: Developmental Origins of Health and Diseases

Drug Formulary: Varying lists of prescription drugs approved by a given health plan for distribution to a covered person through specific pharmacies. Health plans often restrict or limit the type and number of medicines allowed for reimbursement by limiting the drug formulary list. The list of prescription drugs for which a particular employer or State Medicaid program will pay. Formularies are either "closed," including

only certain drugs or "open," including all drugs. Both types of formularies typically impose a cost scale requiring consumers to pay more for certain brands or types of drugs. See also Formulary.

Drug Formulary Database: This EMR feature is used for electronic prescribing, electronic medical record (EMR), and computerized physician order entry (CPOE) systems to present formulary status to the provider while during the prescribing decision.

DSM: Diagnostic and Statistical Manual for Mental Diseases

[E]

EDI: Acronym for Electronic Data Interchange. Electronic communication between two parties, generally for the filing of electronic claims to payers.

EDI Translator: Used in electronic claims and medical record transmissions, this is a software tool for accepting an EDI transmission and converting the data into another format, or for converting a non-EDI data file into an EDI format for transmission. See also Electronic Data Interchange.

EHR/EMR System Designer, Developer, Manufacturer, Vendor, Supplier, Retailer, Re-seller: Any entity that is involved in the design, development, testing, manufacturing, supplying, selling including re-selling of Electronic Health Records or Electronic Medical Records Systems as a whole or part thereof.

Electronic Data Interchange (EDI): The automated exchange of data and documents in a standardized format. In health care, some common uses of this technology include claims submission and payment, eligibility, and referral authorization. This refers to the exchange of routine business transactions from one computer to another in a standard format, using standard communications protocols.

Electronic Health Records (EHR): The one or more repositories, physically or virtually integrated, of information in computer processable form, relevant to the wellness, health and healthcare of an individual, capable of being stored and communicated securely and of being accessible by multiple authorized users, represented according to a standardized or commonly agreed logical information model. Its primary purpose is the support of life-long, effective, high quality and safe integrated healthcare. [ISO 18308:2011]

Electronic Medical Records (EMR): The EMR could be considered as special case of the EHR, restricted in scope to the medical domain or at least very much medically focused [ISO/TR 20514]. The Japanese Association of Healthcare Information Systems (JAHIS) has defined a five-level hierarchy of the EMR; Departmental EMR: contains a patient's medical information entered by a single hospital department (e.g. pathology, radiology, pharmacy); Inter-departmental EMR: contains a patient's medical information from two or more hospital departments; Hospital EMR: contains a patient's clinical information from a particular hospital; Inter-hospital EMR: contains a patient's medical information from two or more hospitals; EHR: longitudinal collection of health information from all sources. [Classification of EMR systems, JAHIS, V1.1, Mar 1996]

Electronic Protected Health Information (ePHI): Electronic Protected Health Information (ePHI) is any protected health information (PHI) that is created, stored, transmitted, or received electronically. Electronic

protected health information includes any medium used to store, transmit, or receive PHI electronically. The following and any future technologies used for accessing, transmitting, or receiving PHI electronically are covered. Media containing data at rest (data storage) like personal computers with internal hard drives used at work, home, or traveling, external portable hard drives, including iPods and similar devices, magnetic tape, removable storage devices, such as USB memory sticks, CDs, DVDs, and floppy disks, PDAs and smartphones and data in transit, via wireless, Ethernet, modem, DSL, or cable network connections, Email, File transfer. (For Protected Health Information – PHI, please see below)

Encounter: A clinical encounter is defined by ASTM as "(1) an instance of direct provider/practitioner to patient interaction, regardless of the setting, between a patient and a practitioner vested with primary responsibility for diagnosing, evaluating or treating the patient's condition, or both, or providing social worker services. (2) A contact between a patient and a practitioner who has primary responsibility for assessing and treating the patient at a given contact, exercising independent judgment." Encounter serves as a focal point linking clinical, administrative and financial information. Encounters occur in many different settings -- ambulatory care, inpatient care, emergency care, home health care, field and virtual (telemedicine).

Episode: An episode of care consists of all clinically related services for one patient for a discrete diagnostic condition from the onset of symptoms until the treatment is complete [http://www.ncmedsoc.org/non_members/pai/PAI-FinalWorkbookforVideo.pdf] Thus, for every new problem or set of problems that a person visits his clinical care provider, it is considered a new episode. Within that episode the patient will have one or many encounters with his clinical care providers till the treatment for that episode is complete. Even before the resolution of an episode, the person may have a new episode that is considered as a distinctly separate event altogether. Thus, there may be none, one or several ongoing active episodes. All resolved episodes are considered inactive. Hence they become part of the patient's past history. A notable point here is that all chronic diseases are considered active and may never get resolved during the life-time of the person, e.g., diabetes mellitus, hypertension, etc.

EPR: Broadly defined, a personal health record is the documentation of any form of patient information–including medical history, medicines, allergies, visit history, or vaccinations–that patients themselves may view, carry, amend, annotate, or maintain. Today, when we refer to PHRs, we typically mean an online personal health record–which may variously be referred to as an ePHR, an Internet PHR, an Internet medical record, or a consumer Internet Medical Record (CIMR). Generally, such records are maintained in a secure and confidential environment, allowing only the individual, or people authorized by the individual, to access the medical information. Not all electronic PHRs are Internet PHRs. PC-based PHRs may be set up to capture medical information offline.

Evidence Based Medicine: Evidence-based medicine (EBM) is the integration of best research evidence with clinical expertise to aid in the diagnosis and management of patients.

[F]

GLOSSARY

Family History: A list of the patient's family medical history including the chronic medical problems of parents, siblings, grandparents, etc.

FHIR: Fast Health Interoperable Resources, the newest version from HL7 org for messaging.

Formatting and Protocol Standards: Data exchange standards which are needed between CPR systems, as well as CPT and other provider systems, to ensure uniformity in methods for data collection, data storage and data presentation. Proactive providers are current in their knowledge of these standards and work to ensure their information systems conform to the standards.

Formulary: An approved list of prescription drugs; a list of selected pharmaceuticals and their appropriate dosages felt to be the most useful and cost effective for patient care. Organizations often develop a formulary under the aegis of a pharmacy and therapeutics committee. In HMOs, physicians are often required to prescribe from the formulary. See also Drug Formulary.

[G]

Growth Chart: A feature for a Primary Care or EMR that can be used for pediatric patients. Age, height, weight, and head measurements can be entered over the patient's lifetime, and the feature creates a line graph.

[H]

Health Care Operations: Institutional activities that is necessary to maintain and monitor the operations of the institution. Examples include but are not limited to: conducting quality assessment and improvement activities; developing clinical guidelines; case management; reviewing the competence or qualifications of health care professionals; education and training of students, trainees and practitioners; fraud and abuse programs; business planning and management; and customer service. Under the HIPAA Privacy Rule, these are allowable uses and disclosures of identifiable information "without specific authorization." Research is not considered part of health care operations.

Health Care, Healthcare: Care, services, and supplies related to the health of an individual. Health care includes preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, among other services. Healthcare also includes the sale and dispensing of prescription drugs or devices.

Health Information: Information in any form (oral, written or otherwise) that relates to the past, present or future physical or mental health of an individual. That information could be created or received by a health care provider, a health plan, a public health authority, an employer, a general health insurer, a school, a university or a health care clearinghouse.

Health Level Seven (HL7): A data interchange protocol for health care computer applications that simplifies the ability of different vendor-supplied IS systems to interconnect. Although not a software program in itself, HL7 requires that each healthcare software vendor program HL7 interfaces for its products. The organization is one of the American National Standards Institute accredited Standard Developing Organization (SDO) - Health Level 7 domain is the standards for electronic interchange of clinical, financial and administrative info among healthcare oriented computer systems. Is a not-for-profit volunteer organization. It develops specifications, most widely used is the messaging standard that enables disparate health care applications to exchange key sets of clinical and administrative data. It promotes the use of standards within and among healthcare organizations to increase the effectiveness and efficiency of healthcare delivery. It is an international community of healthcare subject matter experts and information scientists collaborating to create standards for the exchange, management and integration of electronic healthcare information.

Health: The state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity. It is recognized, however, that health has many dimensions (anatomical, physiological, and mental) and is largely culturally defined. The relative importance of various disabilities will differ depending upon the cultural milieu and the role of the affected individual in that culture. Most attempts at measurement have been assessed in terms or morbidity and mortality.

Healthcare provider: A health care provider is an individual or an institution that provides preventive, curative, promotional or rehabilitative health care services in a systematic way to individuals, families or communities. An individual health care provider may be a health care professional, an allied health professional, a community health worker, any or other person trained and knowledgeable in medicine, nursing or other allied health professions, or public/community health workers like , ASHA, ANM, midwives, paramedical staff, OT/lab/radio-diagnostic technicians, etc. An institution will include hospitals, clinics, primary care centers and other service delivery points of health care individual clinics, polyclinics, diagnostic centers, etc., i.e., any place where a medical record is generated during a patient-care provider encounter (in conformance to CEA 2010 – please refer to Clinical Establishment item above). It must be noted that any person solely performing non-clinical work is not a care provider.

Healthcare Service Provider (HSP): see Healthcare provider

History of Present Illness (HPI): The HPI is the history of the patient's chief complaint.

Human Subject: Refers to a living subject participating in research about whom directly or indirectly identifiable health information or data are obtained or created.

Hybrid Record: Term used for when a provider uses a combination of paper and electronic medical records during the transition phase to EMR.

[I]

Independent Software Vendor (ISV): A company specializing in making or selling software products that runs on one or more computer hardware or operating system platforms.

Immunization: A complete list of all immunizations that the patient has had.

Informatics: The application of computer technology to the management of information.

Integration: Integration allows for secure communication between enterprise applications.

GLOSSARY

Interface: A means of communication between two computer systems, two software applications or two modules. Real time interface is a key element in healthcare information systems due to the need to access patient care information and financial information instantaneously and comprehensively. Such real time communication is the key to managing health care in a cost effective manner because it provides the necessary decision-making information for clinicians, providers, other stakeholders, etc.

International Classification of Diseases: This is the universal coding method used to document the incidence of disease, injury, mortality and illness. A diagnosis and procedure classification system designed to facilitate collection of uniform and comparable health information. The ICD-9-CM was issued in 1979. This system is used to group patients into DRGs, prepare hospital and physician billings and prepare cost reports. Classification of disease by diagnosis codified into six-digit numbers. See also coding.

International Health Terminology Standards Development Organization (IHTSDO): Denmark-based organization that maintains and licenses SNOMED codes worldwide.

Interoperability: The capability to provide successful communication between end-users across a mixed environment of different domains, networks, facilities and equipment.

ISP: Internet Service Provider

ISV (Independent Software Vendor): An independent software vendor (ISV) is a company specializing in making or selling software, designed for mass or niche markets. This typically applies for application-specific or embedded software, from other software producers.

[J]

J-Codes: A subset of the HCPCS Level II code set with a high-order value of "J" that has been used to identify certain drugs and other items.

[L]

LAN (Local Area Network): A LAN supplies networking capability to a group of computers in close proximity to each other such as in an office building, a school, or a home.

Legacy System Integration: The integration of data between a legacy system and some other software program most commonly using HL-7 standards.

Legacy Systems: Computer applications, both hardware and software, which have been inherited through previous acquisition and installation. Most often, these systems run business applications that are not integrated with each other. Newer systems which stress open design and distributed processing capacity are gradually replacing such systems.

Length of Stay (LOS): The duration of an episode of care for a covered person. The number of days an individual stays in a hospital or inpatient facility. May also be reviewed as Average Length of Stay (ALOS).

LEPR (Longitudinal Patient Record): Longitudinal Patient Record is an EHR that includes all healthcare information from all sources.

[M]

Management Information System (MIS): The common term for the computer hardware and software that provides the support of managing the plan.

Master Patient / Member Index: An index or file with a unique identifier for each patient or member that serves as a key to a patient's or member's health record.

Maximum Defined Data Set: All of the required data elements for a particular standard based on a specific implementation specification. An entity creating a transaction is free to include whatever data any receiver might want or need. The recipient is free to ignore any portion of the data that is not needed to conduct their part of the associated business transaction, unless the inessential data is needed for coordination of benefits.

MCI: Medical Council of India

Medical Code Sets: Codes that characterize a medical condition or treatment. These code sets are usually maintained by professional societies and public health organizations. Compare to administrative code sets.

Medical Informatics: Medical informatics is the systematic study, or science, of the identification, collection, storage, communication, retrieval, and analysis of data about medical care services to improve decisions made by physicians and managers of health care organizations. Medical informatics will be as important to physicians and medical managers as the rules of financial accounting are to auditors.

Medical Management Information System (MMIS): A data system that allows payers and purchasers to track health care expenditure and utilization patterns. It may also be referred to as Health Information System (HIS), Health Information Management (HIM) or Information System (IS). See also Electronic Medical Record (EMR).

Metadata and Date Standard (MDDS) – A set of data elements and their specification for use in certain domain, such as health, e-governance.

MIMS: Monthly Index of Medical Specialties

Minimum Data Set: The minimum set of data elements that must be captured, stored, made available for retrieval, presentation, relay and sharing by an EHR system. It comprises of all of the essential data elements required for implementation. An entity creating a transaction must include the mandatory data elements at all times and is free to exclude optional data elements. The entity is free to additionally include whatever other data elements that any receiver might want or need. The recipient is free to ignore any portion of the data that is not mandatory and is further free to ignore any other portion of the data that is not needed to conduct their part of the associated transaction, unless required by sender, intermediaries or receiver. This minimum data set represents the most common data, and system designers are at liberty to add to it as they deem necessary to enrich or enhance their EHR systems.

GLOSSARY

Modifier: Additional character of a code added to an existing code that is used to help in extending or localization of the existing code.

[N]

NANDA: North American Nursing Diagnosis Association

National Council for Prescription Drug Programs: An ANSI-accredited group that maintains a number of standard formats for use by the retail pharmacy industry.

NEMA: The National Electrical Manufacturers Association (NEMA) is the association of electrical equipment and medical imaging manufacturers, founded in 1926 and headquartered in Rosslyn, Virginia.

Non-Participating Physician (or Provider): A provider, doctor or hospital that does not sign a contract to participate in a health plan, usually which requires reduced rates from the provider. In the Medicare Program, this refers to providers who are therefore not obligated to accept assignment on all Medicare claims. In commercial plans, non-participating providers are also called out of network providers or out of plan providers. If a beneficiary receives service from an out of network provider, the health plan (other than Medicare) will pay for the service at a reduced rate or will not pay at all.

[O]

Open Access: A term describing a member's ability to self-refer for specialty care. Open access arrangements allow a member to see a participating provider without a referral from another doctor. Health plan members' abilities, rights or invitation to self refer for specialty care. Also called Open Panel.

openEHR: openEHR is an open standard specification in health informatics that describes the management and storage, retrieval and exchange of health data in electronic health records (EHRs). In openEHR, all health data for a person is stored in a "one lifetime", vendor-independent, person-centered EHR. Maintained by the openEHR Foundation, these are based on a combination of 15 years of European and Australian research and development into EHRs and new paradigms, including what has become known as the archetype methodology for specification of content and include information and service models for the EHR, demographics, clinical workflow and archetypes. They are designed to be the basis of a medico-legally sound, distributed, versioned EHR infrastructure.

OR: Operating Room – synonymous to OT as below

OT: Operation Theatre

OTC: Over the counter (drugs). Refers to those drugs that are available off the shelf without any prescription or advice from a registered medical practitioner

Outcome: A clinical outcome is the "change in the health of an individual, group of people or population which is attributable to an intervention or series of interventions". (Taken from: Frommer, Michael; Rubin, George; Lyle, David (1992)."The NSW Health Outcomes program". New South Wales Public Health Bulletin 3: 135. doi:10.1071/NB92067)

Outpatient Care: Care given a person who is not bedridden. It is also called ambulatory care. Many surgeries and treatments are now provided on an outpatient basis, while previously they had been considered reason for inpatient hospitalization. Some say this is the fastest growing segment of healthcare

[P]

Participating Physician: A primary care physician in practice in the payer's managed care service area who has entered into a contract.

Past History: A list of a patient's past health problems, surgeries and specialists.

Patient Demographics: All patient's pertinent information such as first and last name, SSN, DOB, insurance, etc.

Patient Portal: A secure web-based system that allows a patient to register for an appointment, schedule an appointment, request prescription refills, send and receive secure patient-physician messages, view lab results, pay their bills electronically, access physician directories.

Patient: A person who is under medical care or treatment

PC Based: A program designed to run on an individual PC. This typically means data is not shared in real time among other PCs (users).

PCP: Primary care physician who often acts as the primary gatekeeper in health plans. That is, often the PCP must approval referrals to specialists. Particularly in HMOs and some PPOs, all members must choose or are assigned a PCP.

PHR: A personal health record or PHR is typically a health record that is initiated and maintained by an individual. An ideal PHR would provide a complete and accurate summary of the health and medical history of an individual by gathering data from many sources and making this information accessible online.

Picture Archive Communication System (PACS): Used by radiology and diagnostic imaging organizations to electronically manage information and images

Practice Parameters, Practice Guidelines: Systematically developed statements to standardize care and to assist in practitioner and patient decisions about the appropriate health care for specific circumstances. Practice guidelines are usually developed through a process that combines scientific evidence of effectiveness with expert opinion. Practice guidelines are also referred to as clinical criteria, protocols, algorithms, review criteria, and guidelines. The American Medical Association defines practice parameters as strategies for patient management, developed to assist physicians in clinical decision-making. Practice parameters may also be referred to as practice options, practice guidelines, practice policies, or practice standards.

Prescription Drug: Drug that the law says can only be obtained by prescription.

GLOSSARY

Primary Care Physician: A "generalist" such as a family practitioner, pediatrician, internist, or obstetrician. In a managed care organization, a primary care physician is accountable for the total health services of enrollees including referrals, procedures and hospitalization. Also see Primary Care Provider.

Primary Care Provider: The provider that serves as the initial interface between the member and the medical care system. The PCP is usually a physician, selected by the member upon enrollment, who is trained in one of the primary care specialties who treats and is responsible for coordinating the treatment of members assigned to his/her plan.

Primary Care: Basic or general health care usually rendered by general practitioners, family practitioners, internists, obstetricians and pediatricians who are often referred to as primary care practitioners or PCPs. Professional and related services administered by an internist, family practitioner, obstetrician-gynecologist or pediatrician in an ambulatory setting, with referral to secondary care specialists, as necessary.

Principal Diagnosis: The medical condition that is ultimately determined to have caused a patient's admission to the hospital. The principal diagnosis is used to assign every patient to a diagnosis related group. This diagnosis may differ from the admitting and major diagnoses.

Privacy Standards: The Privacy standards restrict the use & disclosure of individually identifiable health information. Privacy standard applies to all protected health information may it is in physical or electronic form.

Privacy: Privacy means an individual's interest in limiting who has access to personal health care information. Specific patient authorization is required for use and disclosure of clinical notes. As per Fernando & Dawson, 2009, privacy is control of access to private information avoiding certain kinds of embarrassment and can be shared or not shared with others; Only authorized (by the patient) people can view the recorded data or part thereof

Progress Note: The documentation of a patient visit or encounter including all or part of the SOAP format.

Protected health information (PHI): Any individually identifiable information whether oral or recorded in any form or medium that is created, or received by a health care provider, health plan or health care Healthcare provider and relates to past, present, or future physical or mental health conditions of an individual; the provision of health care to the individual; or past, present, or future payment for health care to an individual.

[R]

Real Time: The instantaneous sharing of data among a user group. It is common to a client/server database configuration.

Reference Model (RM):

Referral: Some insurance companies require that on specific plans a referral must be obtained for certain procedures or visits to specialists. The referral is acquired by the primary care physician (PCP) by

contacting the insurance company by phone or mail. This is a request for the service. The referral consists of an authorization code, a number of visits allowed (if applicable) and an expiration date.

Referring Provider: is the provider that referred the patient to a specialist or for a specific procedure.

Regenstrief: The Regenstrief Institute is an international non-profit medical research organization associated with Indiana University. It produces and maintains LOINC codes.

Relational Database: A database program that stores data in a manner similar to Excel, with the difference being the data elements are related (linked) to each other.

Remote Access: Data travels through a private, protected passage via the Internet, allowing healthcare providers to access from home or another practice location and allows EMR vendor to perform system maintenance off-site

Rendering/Performing Provider: The provider actually treating the patient.

Roles and Access Levels: The role and access level of the user needs to be determined and set by the system administrator. The role determines the access level. While roles may be such as system administrator, medical doctor, registered nurse, medical student, medical assistant, nurse assistant, ancillary nurse, health worker, Anganwadi worker (grass-root health worker), etc., the access levels may include viewing only, viewing/adding/editing only, viewing/adding/editing/deleting, all allowed etc. These need to be set out clearly in the SOP of the facility.

ROS (Review of Systems): A series of questions related to the system(s) that the patient is having complaints about (i.e. respiratory for cold symptoms).

RxNorm: RxNorm is the name of a US-specific terminology in medicine that contains all medications available on US market; it provides normalized names for clinical drugs and links its names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software.

[S]

Secondary Care: Services provided by medical specialists who generally do not have first contact with patients (e.g., cardiologist, urologists, dermatologists). In the U.S., however, there has been a trend toward self-referral by patients for these services, rather than referral by primary care providers. This is quite different from the practice in England, for example, where all patients must first seek care from primary care providers and are then referred to secondary and/or tertiary providers, as needed.

Security Standards: The Security Standards require measures to protect the confidentiality, integrity and availability of e-PHI while it's being stored & exchanged. The security standard applies to all electronic PHI.

Security: This refers to the methods and techniques adopted to protect privacy and are a defense mechanism from any attack (Hong et al., 2004)

GLOSSARY

SNOMED: Systemized Nomenclature of Medicine Clinical Terms is the universal health care terminology. It is comprehensive and covers procedures, diseases, and clinical data. SNOMED CT helps to structure and computerize the medical record. It allows for a consistent way of indexing, storing, retrieving and aggregating clinical data across sites of care (i.e. hospitals, doctors offices) and specialties. By standardizing the terminology, the variability in the way data is captured, encoded and used for clinical care of patients and research is reduced. Allows for more accurate reporting of data. It is currently available in English, Spanish and German.

Social History: A description of a patient's social habits and history including marital status, alcohol and drug use and exercise habits.

Solo Practice, Solo Practitioner: A physician who practices alone or with others but does not pool income or expenses. This form of practice is becoming increasingly less common as physicians band together for contracting, overhead costs and risk sharing.

SOP: Standard operating procedures or protocols

SQL: Structured Query Language – is a computer language aimed to store, manipulate and retrieve data stored in relational databases.

SDO: Standards Development Organization – an organization responsible for development and maintenance of a standard or several, usually run on a not-for-profit basis.

Subjective: Section in a progress note where a patient's account of their current problem is documented. Consists of chief complaint, HPI and ROS.

Sx: Abbreviation for symptoms

[T]

T1, T3 line: A high-speed internet connection provided via telephone lines often used by businesses needing internet connection speeds greater than DSL/Cable.

Therapeutic Alternatives: Strong Drug products that provide the same pharmacological or chemical effect in equivalent doses. Also see Drug Formulary.

TPA: Third Party Administrator

Treatment Episode: The period of treatment between admission and discharge from a modality, e.g., inpatient, residential, partial hospitalization, and outpatient, or the period of time between the first procedure and last procedure on an outpatient basis for a given diagnosis. Many healthcare statistics and profiles use this unit as a base for comparisons.

Treatment: The provision of health care by one or more health care providers. Treatment includes any consultation, referral or other exchanges of information to manage a patient's care.

[V]

Vital Statistics: Statistics relating to births (natality), deaths (mortality), marriages, health, and disease (morbidity). Vital statistics for the United States are published by the National Center for Health Statistics. Vital statistics can be obtained from CDC, state health departments, county health departments and other agencies. An individual patient's vital statistics in a health care setting may also refer simply to blood pressure, temperature, height and weight, etc.

VPN: Virtual Private Network – A VPN "tunnel" is a secure connection, typically firewall to firewall that provides for remote access to your data server.

[W]

WHO: The World Health Organization is a specialized agency of the United Nations that is concerned with international public health.

[X]

XML (Extensible Markup Language): Used for defining data elements on a Web page and communication between two business systems. Example: Standard messaging system for and EMR to integrate with another software such as a practice management or drug formulary database.

CONTACT INFORMATION

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Implementation specific queries may be referred to:
National Release Center (NRC)
HPC-Medical & Bioinformatics Application Group,
Centre for Development of Advanced Computing (C-DAC)
Savitribai Phule Pune University Campus
Ganeshkhind Road
Pune – 411007
Email: nrc-help@cdac.in
http://www.snomedctnrc.in

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Ministry of Health & Family Welfare

Meta Data for Documents

Name of Division:

S.no	Item	Information to be Displayed
1.	Document title to be displayed on website	Revised Electronic Health Record (EHR) Standards for Ind
2.	Division/Autonomous Body (Contact E-mail-id)	(e-Governance Division) dir.ehealth@gmail.com
3.	Language (English)	Hindi
4.	Form of Document (e.g. pdf,doc,xls) (zip format not allowed)	PDF
5.	Reference URL or Detailed PDF	
6.	Validity	1 Month (upto 20th May 2016)
7	Name & Email-Id of Sender	Sh. Jitendra Arora, Director (eGov) dir.ehealth@gmai
8	Section of Website, where it is to be uploaded	Programme/Reports/News & Highlights/Key Developments/Disease Alerts/Event Announcements/Vacancies

- Kindly check & ensure that contents have been uploaded as New ☐ or Update ☐ or Deleted ☐ at the relevant section of the website.

Signature:
Name of Nodal Officer: Sh. Jitendra Arora
Designation: Director (eGov)
Email-Id: dir.ehealth@gmail.com
Contact No: 23062317

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F.No Q-11011/3/2015-eGov

Government of India
Ministry of Health & Family Welfare
(e-Governance Division)

***

New Delhi, dated the 18th **March, 2016**

NOTICE

Subject: **Placing the Electronic Health Record (EHR) Standards for India on public domain for comments/views-reg.**

In 2013, Ministry of Health and Family Welfare notified Electronic Health Records (EHR) Standards for India. The set of Standards given therein were chosen from the best available and used standards applicable to EHRs from around the world keeping in view their suitability and applicability in India. Now these Standards have been improvised and made according to the ever changing need of the mass. Accordingly, the revised EHR Standards for India which has been notified in February, 2016 have been placed in public domain with a view to elicit comments/views of the stakeholders including the general public.

The comments/views may be forwarded to Director (e-Governance Division), Ministry of Health and Family Welfare, Room No 307-D, Nirman Bhawan, New Delhi-110108 or emailed at jitendra.arora@gov.in **on or before 20th April, 2016**.

(Jitendra Arora)
Director
MoHFW
Phn No. 23062317

Subject: **Fwd: Minutes of the Third Meeting of the EHR Standards Review Committee held on 24.02.2016**
Date: 03/07/16 11:28 AM
From: "Ashish Sharma" <ashish.sharma91@gov.in>
To: supten@gmail.com, sbbhattacharyya@gmail.com, kbhatia@gov.in, Ddei.dey@gmail.com, gaurs@cdac.in, bedi11@yahoo.com, Sunil Kumar <sunil.bhushan@gov.in>, drkaranvir_s@apollohospitals.com, shobha.mishra@ficci.com, narwalr@who.int, dr.amitmishra@gmail.com
Cc: asfnd.kb@gmail.com, sunil.sharma62@gov.in, dir.ehealth@gmail.com, amit.k89@gov.in, chandrasens@deloitte.com, bhanuprakash@deloitte.com

MOM_EHR_STANDARDS_REVIEW_MEETING_01032016_VER2_201... (275kB)

Respected Sir,

Kindly find attached minutes of the Third Meeting of the Electronic Health Record (EHR) Standards Review Committee held on 24th February 2016 at 11:00AM under the Chairmanship of Shri Sunil Sharma, JS (eGovernance), MoHFW.

Regards

Ashish Sharma
ASO (eGov)

341

Department of Health & Family Welfare
e-Governance Division

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Subject: Minutes of the Third Meeting of the Electronic Health Record (EHR) Standards Review Committee held on 24th February, 2016

The third meeting of 'EHR Standards Review Committee' was held on 24th February, 2016 at 11:00 A.M. in the Room No.406, A –Wing, Nirman Bhawan, Ministry of Health & Family Welfare under the chairmanship of Shri Sunil Sharma, JS (eGovernance). Representatives from DCGI office attended the meeting as special invitees. The list of participants is placed at **Annexure** - **A**.

2. Shri Sunil Sharma, JS (eGov) welcomed the participants. He thereafter requested Shri Jitendra Arora, Director (eGov) to start the proceedings.

3. Director (eGov) briefed the participants about the progress made so far & requested the committee members to share their opinions on the comments received on the draft revisions proposed in EHR Standards (2013). The draft revisions were discussed in the last meeting held on 14th December, 2015.

4. The comments obtained from the members were discussed in the meeting and clarified by Shri B.S. Bedi and Shri S.B. Bhattacharya. It was opined that some of the standards related to statistical data exchange, health information exchange etc. such as SDMX (Statistical Data and Metadata eXchange), Open MPI (Master patient Index), Open HIE architecture etc. may be referred to as appropriate.

5. JS (e Gov) enquired about the availability of comprehensive Drug directory for use in EHR system. The representatives from DCGI office informed the chair that the states have database of drugs but the same may not be readily available in electronic format.

6. It was informed by Shri B.S. Bedi that iNRC, CDAC, Pune is working on creation of drug database required for use in EHR system. DCGI office may be requested to provide the available drug database information to iNRC.

7. Based on detailed discussions, the following decisions were taken in the meeting:

- The Committee approved the Draft Revised EHR Standards (Copy at Annexure B). It was decided that Draft Standards may be placed in public domain for a period of 30 days with the approval of competent authority.

- FICCI may be requested to manage secretarial tasks for collation, review etc. of comments / suggestions received from public domain and presentation of the same to committee.

- DCGI office may provide the drug directory structure and details to eGovernance Division on attributes such as brand name, generic name, formulation, side effects etc.

The meeting ended with vote of thanks to the chair and the participants.

Annexure – A 339

List of Participants:

1. Shri Sunil Sharma, JS, MoHFW.... Chairman
2. Shri Jitendra Arora,Director(eGov),MoHFW
3. Shri Sunil Kumar, STD (NIC), MoHFW
4. Dr S B Bhattacharya, Head(Health Informatics), TCS
5. Shri B S Bedi, Adviser,CDAC
6. Prof S N Sarbadhikari, Project Director,CHI of NHP, NIHFW
7. Dr Karanvir Singh, CMIO, Apollo Hospitals
8. Shri Rajesh Narwal, Technical Officer,WHO
9. Shri Chandrasen, PL (ePMU), MoHFW
10. Shri Bhanu Prakash, Consultant eGov, MoHFW

338

Department of Health & Family Welfare

e-Governance Division

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Subject: Minutes of the ThirdMeeting of the Electronic Health Record (EHR) Standards Review Committee held on 24thFebruary, 2016

The third meeting of 'EHR Standards Review Committee' was held on 24thFebruary, 2016 at 11:00 A.M. in the Room No.406, A –Wing, NirmanBhawan, Ministry of Health & Family Welfare under the chairmanship of ShriSunil Sharma, JS (eGovernance). Representatives from DCGI office attended the meeting as special invitees. The list of participants is placed at **Annexure - A**.

2. ShriSunil Sharma, JS (eGov)welcomed the participants. Hethereafter requestedShri Jitendra Arora, Director (eGov) to start the proceedings.

3. Director (eGov) briefed the participants about the progress made so far &requested the committee members to share their opinions onthe comments received onthe draft revisions proposed in EHR Standards (2013). The draft revisions were discussed in the last meeting held on 14th December, 2015.

4. The comments obtained from the members were discussed in the meeting and clarified by Shri B.S. BediandShri S.B. Bhattacharya. It was opined that some of the standards related to statistical data exchange, health information exchange etc. such as SDMX (Statistical Data and Metadata eXchange), Open MPI (Master patient Index), Open HIE architecture etc. may be referred to as appropriate.

5. JS (e Gov) enquired about the availability of comprehensive Drug directory for use in EHR system.The representatives from DCGI office informed the chair that thestates have database of drugs but the same may not be readily available in electronic format.

6. It was informed by Shri B.S. Bedi that iNRC, CDAC, Pune is working on creation of drug database required for use in EHR system. DCGI office may be requested to providetheavailable drug database information to iNRC.

337

7. Based on detailed discussions, the following decisions were taken in the meeting:

- The Committee approved the Draft Revised EHR Standards (Copy at Annexure B). It was decided that Draft Standards may be placed in public domain for a period of 30 days with the approval of competent authority.

- FICCI may be requested to manage secretarial tasks for collation, review etc. of comments / suggestions received from public domain and presentation of the same to committee.

- DCGI office may provide the drug directory structure and details to eGovernance Division on attributes such as brand name, generic name, formulation, side effects etc.

The meeting ended with vote of thanks to the chair and the participants.

Annexure – A

336

List of Participants:

1. Shri Sunil Sharma, JS,MoHFW.... Chairman
2. Shri JitendraArora,Director(eGov),MoHFW
3. Shri Sunil Kumar,STD (NIC),MoHFW
4. Dr S B Bhattacharya, Head(Health Informatics), TCS
5. Shri B S Bedi, Adviser,CDAC
6. Prof S N Sarbadhikari,ProjectDirector,CHI of NHP, NIHFW
7. DrKaranvir Singh, CMIO, Apollo Hospitals
8. Shri Rajesh Narwal, Technical Officer,WHO
9. Shri Chandrasen, PL (ePMU), MoHFW
10. Shri Bhanu Prakash, ConsultanteGov, MoHFW

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335

e-Governance Division
Department of Health & Family Welfare
Ministry of Health & Family Welfare
Government of India
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ELECTRONIC HEALTH RECORD (EHR) STANDARDS FOR INDIA

FEBRUARY 2016

Revised recommendations (over original August 2013 recommendations)

TABLE OF CONTENTS

333

TABLE OF CONTENTS

Contents

Executive Summary 1
Standards at a Glance 3
Standards and Interoperability 7
Health Record IT Standards 9
Guidelines 16
Data Ownership of Health Records 18
Data Privacy and Security 23
Glossary 28
Contact Information 44

332

EXECUTIVE SUMMARY

Executive Summary

INTRODUCTION

In September 2013 the Ministry of Health & Family Welfare (MoH&FW) notified the Electronic Health Record (EHR) Standards for India. The set of standards given therein were chosen from the best available and used standards applicable to Electronic Health Records from around the world keeping in view their suitability and applicability in India. The Committee constituted to recommend the standards drew from experts, practitioners, government officials, technologists, and industry. The notified standards were not only supported by professional bodies, regulatory bodies, stakeholders, but various technical and social commentators as well as being a step in the right direction. MoH&FW moved ahead with facilitating the adoption, as next steps, and in last two years the Ministry has made available standards like SNOMED CT free for use in country as well as appoint interim National Release Center (NRC) to handle this clinical terminology standard that is fast gaining widespread acceptance amongst the various healthcare IT stakeholder communities worldwide.

At the time of notifying the standards in September 2013, it was understood that the standards themselves will continue to evolve over time. Consequently, it was accepted that this notification will require revision from time to time. This becomes all the more necessary as understanding of those standards, their implementation and the expectations from the healthcare systems improve. Hence, MoH&FW constituted an expert group to review the earlier notified set of standards based on the experience and eyes firmly on the future. The set of standards provided herein represents the recommendations of the Expert Committee arrived at after deliberating on the various aspects of standardizations in healthcare record systems. The Committee also carefully examined the provisions of open standards and the guidelines as per the norms suggested by DeitY, MCIT, Government of India and recommended the standards given later in the document.

NEED FOR ELECTRONIC HEALTH RECORD

For a health record of an individual to be clinically meaningful it needs to be from conception or birth, at the very least. As one progresses through one's life, every record of every clinical encounter represents a health-related event in one's life. Each of these records may be insignificant or significant depending on the current problems that the person is suffering from. Thus, it becomes imperative that these records be available, arranged, and be clinically relevant to provide a summary of the various clinical events in the life of a person.

An Electronic Health Record (EHR) is a collection of various medical records that get generated during any clinical encounter or events. With rise of self-care and homecare devices and systems, meaningful healthcare data get generated 24x7 and also have long-term clinical relevance. The purpose of collecting medical records, as much as possible, are manifold – better and evidence based care, increasingly accurate and faster diagnosis that translates into better treatment at lower costs of care, avoid repeating unnecessary investigations, robust analytics including predictive analytics to support personalized care, improved health policy decisions based on better understanding of the underlying issues, etc., all translating into improved personal and public health.

331

EXECUTIVE SUMMARY

Without standards, a lifelong medical record is simply not possible, as different records from different sources spread across ~80+ years potentially needs to be brought meaningfully together. To achieve this, a set of pre-defined standards for information capture, storage, retrieval, exchange, and analytics that includes images, clinical codes and data is imperative.

STRATEGIC HIGHLIGHTS

This document provides a structured overview of the key EHR standards with respect to Indian healthcare system. For every aspect of data/information that is part of any healthcare record system has been addressed with a short guideline regarding implementation included. Various non-related recommendations from previous edition have been removed to better streamline the set of standards selected and achieve harmony among them. A detailed recommendation on the interoperability and standards, clinical informatics standards, data ownership, privacy and security aspects, and the various coding systems are given. The set of standards given in earlier edition has been updated with their latest versions as we move towards a better implementation.

LOOKING AHEAD

This document is a continuation of its earlier version, but in many ways reflects our growing confidence in path correctly chosen earlier – set of international and proven standards focused towards syntactic and semantic interoperability. The idea that any person in India can go to any health service provider/practitioner, any diagnostic center or any pharmacy and yet be able to access and have fully integrated and always available health records in an electronic format is not only empowering but also vision for efficient 21st century healthcare delivery.

In conclusion, it must be reiterated that these standards cannot be considered either in isolation or as "etched in stone for all eternity". These will need to undergo periodic review and update as necessary. Hence, this document must be a "living document".

STANDARDS AT A GLANCE

Standards at a Glance

This section is provided for quick reference. Details are provided in the subsequent sections. N.B., this is a tentative list only.

S. No.	Type	Standard Name	Intended Purpose
1	Identification & Demographics	ISO/TS 22220:2011 Health Informatics – Identification of Subjects of Health Care	Basic identity details of patient
2		MDDS – Demographic (Person Identification and Land Region Codification) version 1.1	Complete demographic for interoperability with E-Governance systems
3	Patient Identifiers	UIDAI Aadhaar	Preferable identifier where available
4		Local Identifier	Identifier given within institution / clinic / lab
5		Government Issued Photo Identity Card Number	Identifier in conjunction with local in absence of Aadhaar
6	Architecture Requirements	ISO 18308:2011 Health Informatics – Requirements for an Electronic Health Record Architecture	System architectural requirements
7	Functional Requirements	ISO/HL7 10781:2015 Health Informatics - HL7 Electronic Health Records-System Functional Model Release 2 (EHR FM)	System functional requirements
8	Reference Model and Composition	ISO 13940 Health informatics - System of Concepts to Support Continuity of Care	Concepts for care, actors, activities, processes, etc.
9		ISO 13606 Health informatics - Electronic Health Record Communication (Part 1 through 3)	Information model architecture and communication
10		openEHR Foundation Models Release 1.0.2	Structural definition and composition
11	Terminology	SNOMED Clinical Terms (SNOMED CT)	Primary terminology
12	Coding System	Logical Observation Identifiers Names and Codes (LOINC)	Test, measurement, observations
13		WHO Family of International Classifications (WHO-FIC) including ICD, ICF, ICHI, ICD-O	Classification and reporting

STANDARDS AT A GLANCE

S. No.	Type	Standard Name	Intended Purpose
14	Imaging	Digital Imaging and Communications in Medicine (DICOM) PS3.0-2015	Image, waveform, audio/video
15	Scanned or Captured Records	JPEG lossy (or lossless) with size and resolution not less than 1024px x 768px at 300dpi	Image capture format
16		ISO/IEC 14496 - Coding of Audio-Visual Objects	Audio/Video capture format
17		ISO 19005-1 Document Management - Electronic Document File Format for Long-Term Preservation - Part 1: Use of PDF 1.4 (PDF/A-1)	Scanned documents format
18	Data Exchange	ANSI/HL7 V2.8.2-2015 HL7 Standard Version 2.8.2 - An Application Protocol for Electronic Data Exchange in Healthcare Environments	Event/Message exchange
19		ASTM/HL7 CCD Release 1 (basis standard ISO/HL7 27932:2009)	Summary Records exchange
20		ISO 13606-5:2010 Health informatics - Electronic Health Record Communication - Part 5: Interface Specification	EHR archetypes exchange [Also, refer to openEHR Service Model specification]
21		DICOM PS3.0-2015 (using DIMSE services & Part-10 media/files)	Imaging/Waveform Exchange
22	Other Relevant Standards	Bureau of Indian Standards and its MHD-17 Committee	Standards Development Organizations (SDOs)
23		ISO TC 215 set of standards	
24		IEEE/NEMA/CE standards for physical systems and interfaces	
25	Discharge/ Treatment Summary	Medical Council of India (MCI) under regulation 3.1 of Ethics	Composition as prescribed
26	E-Prescription	Pharmacy Practice Regulations, 2015 Notification No. 14-148/ 2012- PCI as specified by Pharmacy Council of India	Composition as prescribed
27	Personal Healthcare and medical Device Interface	IEEE 11073 health informatics standards and related ISO standards for medical devices	Device interfacing
28	Data Privacy and Security	ISO/TS 14441:2013 Health Informatics – Security & Privacy Requirements of EHR Systems for Use in Conformity Assessment	Basis security and privacy requirements

STANDARDS AT A GLANCE

S. No.	Type	Standard Name	Intended Purpose
29	Information Security Management	ISO/DIS 27799 Health informatics - Information Security Management in Health using ISO/IEC 27002	Overall information security management
30	Privilege Management and Access Control	ISO 22600:2014 Health informatics - Privilege Management and Access Control (Part 1 through 3)	Access control
31	Audit Trail and Logs	ISO 27789:2013 Health informatics - Audit trails for Electronic Health Records	Audit trail
32	Data Integrity	Secure Hash Algorithm (SHA) used must be SHA-256 or higher	Data Hashing
33	Data Encryption	Minimum 256-bits key length	Encryption key
34		HTTPS, SSL v3.0, and TLS v1.2	Encrypted connection
35	Digital Certificate	ISO 17090 Health informatics - Public Key Infrastructure (Part 1 through 5)	Digital certificates use and management

***Note**: Where year of publication or version of standard (or its parts) is not provided explicitly, the latest published version of standard (or its parts) available from standard body as on the date of notification / circulation of this recommendation is to be used.*

327

List of Supporting / Complimenting Standards

The following list is indicative and representative and not comprehensive or definitive. These standards are advised to be used where applicable and as required

S. No.	Standard	Description
1	ISO 12967:2009	Health Informatics - Service Architecture (Parts 1 - 3)
2	ISO 13972:2015	Health Informatics - Detailed Clinical Models, Characteristics and Processes
3	ISO 20301:2014	Health Informatics - Health Cards - General Characteristics
4	ISO 21090:2011	Health Informatics - Harmonized Data Types for Information Interchange
5	ISO 8601:2004	Data elements and Interchange Formats - Information Interchange - Representation of Dates and Times
6	ISO 13119:2012	Health Informatics - Clinical Knowledge Resources - Metadata
7	ISO 22857:2013	Health Informatics – Guidelines on Data Protection to Facilitate Trans-Border Flows of Personal Health Data
8	ISO 21549-1:2013	Health Informatics — Patient Healthcard Data — Part 1: General Structure
9	ISO TS 14265:2011	Classification of Purposes for Processing Personal Health Information
10	ISO TS 27527:2010	Health Informatics – Provider Identification

STANDARDS AND INTEROPERABILITY

Standards and Interoperability

INTEROPERABILITY STANDARDS

The primary aim of interoperability standards is to ensure syntactic (structural) and semantic (inherent meaning) interoperability of data amongst systems at all times. The need for that cannot be overstated, more so within healthcare information systems whose primary aim is to deliver life-long clinical care at all times so that the person being cared for is able to maintain his/her health.

The set of standards outlined in this document represents an incremental approach to adopting standards, implementation specifications; criteria to enhance the interoperability, functionality, utility, and security of health information technology; and to support its widespread adoption. It is to be kept in mind that these standards need to be flexible and modifiable to adapt to the demographic and resource variance observed in a country like India with its large population with diverse culture that is spread across a large region of varied geographical landscapes – hilly regions, river basins, desert, coast, etc. – many of which are remote and accessible with difficulty.

It is important to recognize that interoperability and standardization can occur at many different levels. To achieve interoperability, information models would need to be harmonized into a consistent representation.

In other cases, organizations may use the same information model, but use different vocabularies or code sets (for example, SNOMED CT or ICD10) within those information models. To achieve interoperability at this level, standardizing vocabularies, or mapping between different vocabularies may be necessary. For some levels, (such as the network transport protocol), an industry standard that is widely used (e.g. TCP/IP – Transmission Control Protocol and Internet Protocol) will likely be the most appropriate. Ultimately, to achieve true interoperability, it is anticipated that multiple layers – network transportation protocols, data and services descriptions, information models, and vocabularies and code sets – will need to be standardized and/or harmonized to produce an inclusive, consistent representation of the interoperability requirements.

It is further anticipated that using a harmonization process will integrate different representations of health care information into a consistent representation and maintain and update that consistent representation over time. For an information model, this process could include merging related concepts, adding new concepts, and mapping concepts from one representation of health care information to another. The need to support standardization of data and services descriptions and vocabularies and codes sets is appropriately addressed.

It is also recognized that a sustainable and incremental approach to the adoption of standards will require processes for harmonizing both current and future standards. This will allow the incremental updating of the initial set of standards, implementation specifications, and certification criteria and provide a framework to maintain them. The decision to adopt such updates will be informed and guided by recommendations from an appropriate authority such as the proposed National eHealth Authority (NeHA), Ministry of Health & Family Welfare or expert groups.

STANDARDS AND INTEROPERABILITY

GOALS

The goals of standards in electronic health record systems are:

- Promote interoperability and where necessary be specific about certain content exchange and vocabulary standards to establish a path forward toward semantic interoperability
- Support the evolution and timely maintenance of adopted standards
- Promote technical innovation using adopted standards
- Encourage participation and adoption by all vendors and stakeholders
- Keep implementation costs as low as reasonably possible
- Consider best practices, experiences, policies and frameworks
- To the extent possible, adopt standards that are modular and not interdependent.

324

Health Record IT Standards

IDENTIFICATION AND DEMOGRAPHIC INFORMATION OF PATIENT

Demographic information including a unique identifier is necessary in a health record system in order to capture identifying information as well as identifiers for linking other medical artifacts logically as well as physically. All health record systems must therefore adhere to the following standards for capturing information related to patient demography and identifiers:

1. ISO/TS 22220:2011 Health Informatics – Identification of Subjects of Health Care
2. MDDS – Demographic (Person Identification and Land Region Codification) version 1.1 from E-Governance Standards, Government of India

Implementation Guideline: Implementers must insure that health record application is able to capture all data fields as provided in the above two standards for completeness. It should also ensure that the system is able to interoperate (receive/import/send/export) all demographics information as provided in above two standards as per demand, i.e. when requested for demographics data in MDDS compliant format it should generate artefacts (file, message, etc.) as per that standard. Where codes related to location, authority, type of organization etc. are required, they should be taken from the MDDS-Demographic Standard.

A health record system must have provision to include patient identifiers of following types:

1. UIDAI Aadhaar Number (preferred where available)
2. Both of following in case Aadhaar is not available:
   2.1 Local Identifier (as per scheme used by HSP)
   2.2 Any Central or State Government issued Photo Identity Card Number

Implementation Guidelines:

1. Implementers must ensure that the Aadhaar number, where that is available, be used as the preferred identifier to serve as the unique health identifier. In case the Aadhaar number is not available, the system should allow a user to insert more than one (minimum two) identifiers for each patient along with its scope and provider (as given in above mentioned patient demography standards) in the system. In emergency situations where identity of patient cannot be confirmed or ascertained, temporary identifiers may be used (as per scheme used by HSP) and later confirmed identifiers may be inserted (while making earlier ones as inactive).
2. *Identification of Patient across EHR systems*: Due to lack of mandate for use of Aadhaar or any such alternative(s) national unique identifier, it is difficult to match patient records when exchanging them between two EHR systems. This may lead to situations where different combinations of local identifier and photo identity card numbers of the same person are used at different locations and/or in solutions.

323

Thus, a single person may get to have different identities under which his/her records are captured. A conflict resolution process may be required to help resolve such cases. At this time, there is no direct solution available other than to use smart (possibly heuristic) algorithms to attempt to match records without or with intervention/confirmation of a human supervisor. Such an algorithm may use name (phonetic or spelling), address (full or parts), date of birth / age, gender, or other such matching details to mark incoming or searched records as possible or exact match before amalgamation or subsequent use. ISV may additionally need to provide the ability to merge/demerge patients to support this process within their solutions.

ARCHITECTURE REQUIREMENTS AND FUNCTIONAL SPECIFICATIONS

A health record system must meet architectural requirements and functional specifications to remain faithful to the needs of service delivery, be clinically valid and reliable, meet legal and ethical requirements, and support good medical practices. Therefore, a health record system must conform to the following standards:

1. ISO 18308:2011 Health Informatics – Requirements for an Electronic Health Record Architecture
2. ISO/HL7 10781:2015 Health Informatics - HL7 Electronic Health Records-System Functional Model Release 2 (EHR FM)

Implementation Guideline: Above two standards, despite being extensive, are not full set of specifications and requirements to be met by a health record system or its many variants (PHR, etc.) or all possible use cases. The above mentioned standards are to be used as minimum set to be used within the scope of implementation as per relevance to the system being developed / deployed.

LOGICAL INFORMATION REFERENCE MODEL AND STRUCTURAL COMPOSITION

A health record system must accumulate observable data and information for all clinically relevant events and encounters. For this purpose, it is important to have common semantic and syntactic logical information model and structural composition for captured artefacts. Unless the data being captured is standardized, its communication and understanding may not be same across systems. Therefore, a health record system must conform to the following standards:

1. ISO 13940 Health Informatics - System of Concepts to Support Continuity of Care
2. ISO 13606 Health Informatics - Electronic Health Record Communication (Part 1 though3)
3. openEHR Foundation Models Release 1.0.2
    3.1 Required Model Specifications: Base Model, Reference Model, Archetype Model
    3.2 Optional Model Specifications: Service Model, Querying, Clinical Decision Support

Implementation Guideline: The ISO 13940 (also known as CEN ContSys) is to be generally used for purpose of modelling and describing concept system and organize information objects. While ISO 13606 set of

322

standards are basic reference model and related specifications, openEHR provides ISO 18308 conformant platform-independent implementation harmonized with ISO 13606 standard. Implementers are free to design internal structures, databases, and user interfaces as per the requirements and technology platforms but structural composition for clinical data/information artefact must be logically similar to Reference Model given in above standards. A health record system implementation must make its openEHR compliant Operational Templates (OPT) freely available and accessible in required format.

MEDICAL TERMINOLOGY AND CODING STANDARDS

In order to have semantic interoperability between different health record systems, it is necessary to follow a common terminology and coding system standards to express unambiguous meaning of data captured, stored, transmitted, and analyzed. It is also important to have these terminologies and codes in computer process-able format to aid automation and ensure that data is in an analyzable state at all times. Therefore, a health record system must conform to the following standards:

1. Primary Terminology: IHTSDO - SNOMED Clinical Terms (SNOMED CT)

Implementation Guideline: A health record system must use SNOMED CT as the primary internal encoding system for all clinically relevant, including dental, nursing, substance/drugs, information. IHTSDO SNOMED CT code shall also be used while communicating clinical information to other health record systems. SNOMED CT concept codes (as pre-coordinated or as post-coordinated expressions) are to be used for all hierarchies covered under the standard unless otherwise provided in this document. It shall also be the coding system that must be used internally in other information storage and communication standards such as openEHR archetypes, HL7, DICOM, etc. IHTSDO releases SNOMED CT twice annually.

2. Test, Measurement and Observation Codes: Regenstrief Institute - Logical Observation Identifiers Names and Codes (LOINC)

Implementation Guideline: LOINC coding is to be used for processing results and reports with Laboratory and Imaging Information Systems. N.B.: SNOMED CT to LOINC coding interchange map is available from IHTSDO and Regenstrief Institute.

3. Classification Codes: WHO Family of International Classifications (WHO-FIC)

    3.1 WHO ICD-10: International Classification of Diseases (ICD) and its derivative classifications

    3.2 WHO ICF: International Classification of Functioning, Disability and Health (ICF)

    3.3 International Classification of Health Interventions (ICHI)

    3.4 International Classification of Diseases for Oncology (ICD-O)

Implementation Guideline: WHO FIC codes are primarily used for aggregated information and statistical/epidemiological analysis for public health purposes derived from health records that contain patient care related information as well as information that is crucial for management, health financing and

321

general health system administration. While SNOMED CT is to be used by health record systems for terminology, generated classification-based reports may require the use of WHO FIC codes. Classification based reporting, for statistical or regulatory purposes, may continue to use WHO FIC codes as mandated by the health regulatory, intelligence, and various research bodies. N.B.: SNOMED CT to ICD-10 coding interchange map is available from IHTSDO and WHO.

DATA STANDARDS FOR IMAGE, MULTIMEDIA, WAVEFORM, DOCUMENT

A health record system stores data records and files of various types in support of clinical functions. These data elements serve the purpose of documentary records of various diagnostic and prescriptive data or information generated. Therefore, a health record system must conform to the following standards for such data:

1. NEMA Digital Imaging and Communications in Medicine (DICOM) PS3.0-2015

Implementation Guideline: NEMA DICOM PS3.0-2015 is a comprehensive standard for handling and managing image (series or single), waveforms (such as those in ECG/EEG), audio (such as those in digital-stethoscope) and video (such as those in endoscope, ultrasound) data in medicine. A health record implementation is required to implement relevant DICOM Information Object Definitions (IODs) for supported data types in Part-10 compliant files. Where required and relevant, other features of standard such as services, display, print, and workflow may be implemented.

2. Scanned or Captured Records:

    2.1 Image: JPEG lossy (or lossless) with size and resolution not less than 1024px x 768px at 300dpi

    2.2 Audio/Video: ISO/IEC 14496 - Coding of Audio-Visual Objects

    2.3 Scanned Documents: ISO 19005-1 Document Management - Electronic Document File Format for Long-Term Preservation - Part 1: Use of PDF 1.4 (PDF/A-1)

Implementation Guideline: The above mentioned standards are to be used for documentary data (scan for prescription, summaries, etc.) and data captured through traditionally non-DICOM compliant sources like picto-micrographs, pathological photographs, photographs of intramural and extramural lesions, etc. All data formats that can be converted into relevant DICOM format should be, as relevant, converted and communicated as secondary captured DICOM format. It may be noted that while no maximum image resolution has been prescribed, a sufficiently acceptable limit may be used to avoid unnecessarily large file that do not aid in correspondingly better diagnosis or analysis.

DATA EXCHANGE STANDARDS

A health record system has to operate in a larger ecosystem of other components with which it must share or communicate data in order to capture and provide as comprehensible medical information as is practical. A health record system must therefore conform to the following standards:

HEALTH RECORD IT STANDARDS

1. Event/Message Exchange: ANSI/HL7 V2.8.2-2015 HL7 Standard Version 2.8.2 - An Application Protocol for Electronic Data Exchange in Healthcare Environments
2. Summary Records Exchange: ASTM/HL7 CCD Release 1 (basis standard ISO/HL7 27932:2009)
3. EHR Archetypes: ISO 13606-5:2010 Health informatics - Electronic Health Record Communication - Part 5: Interface Specification [Also, refer to openEHR Service Model specification]
4. Imaging/Waveform Exchange: NEMA DICOM PS3.0-2015 (using DIMSE services& Part-10 media/files)

Implementation Guideline: Implementation of exchange standards is expected to be at least for the scope of data captured or retained by the health record system. To explain further, full implementation of ANSI/HL7 V2.8.2 for each event and message is not required in health record systems but minimum implementation supporting the types of events and messages relevant to the system is required. Similarly, implementation/support of DICOM DIMSE C-Store and/or C-FIND/C-GET service is expected for IODs supported by health record system whereas implementation of WADO could be optional.

OTHER STANDARDS RELEVANT TO HEALTHCARE SYSTEMS

Healthcare record systems need to co-exist within a larger ecosystem with various other systems. It is important for all systems within a healthcare setup to adhere to relevant standards. While standards related to such systems are not within the scope of this document, as a general rule, standards created or ratified by following Standard Development Organizations (SDOs) should be used:

1. Bureau of Indian Standards and its MHD-17 Committee
2. ISO TC 215 set of standards
3. IEEE/NEMA/CE standards for physical systems and interfaces

Implementation Guideline: To help the implementers, an indicative list of such standards is provided in the "Standards at a Glance" section above. BIS approved standards shall be preferred for implementation.

DISCHARGE/TREATMENT SUMMARY FORMAT

Implementers must ensure that the logical information model includes data elements to satisfy requirements of the format for Medical Records as specified by Medical Council of India (MCI) under regulation 3.1 of ethics. The printed reports will need to be in the MCI prescribed format whenever any discharge or treatment summary is prepared.

E-PRESCRIPTION

Pharmacy Council of India (PCI) has, in its recent regulation (Pharmacy Practice Regulations, 2015 Notification No. 14-148/ 2012- PCI), provided the definition of the term under Section 2(j) that the term

319

'Prescription' includes the term 'electronic direction'. Implementers must therefore ensure that the logical information model includes data elements to satisfy requirements of the format for Medical Prescription as specified by the Pharmacy Council of India. The printed prescription will need to be in the PCI prescribed format whenever any medical prescription meant for drug dispensing is prepared. For the purpose of e-Prescription, implementers must ensure that the electronic version is digitally signed by a registered medical practitioner, and its non-repudiation is ensured at all times. The pharmacists shall be able to print a copy of e-Prescription in the required format along with other relevant digital authentication details.

PERSONAL HEALTHCARE AND MEDICAL DEVICES INTERFACING

Where not covered under relevant data exchange standards, it is recommended that IEEE 11073 health informatics standards and related ISO standards for medical devices be followed as appropriate whenever any personal healthcare/medical device is interfaced with the EMR system for the purpose of clinical data exchange, retrieval, storage, etc.

PRINCIPLES OF DATA CHANGE

The data once entered into a health record system must become immutable. The healthcare provider may have the option to re-insert/append any record in relation to the medical care of the patient as necessary with a complete audit trail of such change maintained by system. Alteration of the previously saved data should not be permitted. No *update* or *update like* command shall be accessible to user or administrator to store a medical record or part thereof. Any record requiring revision should create a new medical record containing the changed/appended/modified data of earlier record. This record shall then be stored and marked as ACTIVE while rendering the previous version(s) of the same record marked INACTIVE. The data will thus be immutable. A strict audit trail shall be maintained of all activities at all times that may be suitably reviewed by an appropriate authority like auditor, legal representatives of the patient, the patient, healthcare provider, privacy officer, court appointed/authorized person, etc.

As-Is Principal:

The data captured through the devices is usually in a certain format whereas the data given by the doctor as file may be in some different format. These data provided / included in the system is to be treated as sacrosanct. The As-Is Principal requires that the data captured in the first instance should be retrievable at any given point of time later in the same format, clarity, size and detail as it was provided in the beginning.

It effectively means that the system is not allowed to make any changes either to the data or its format or its nature at any point other than the creation time for any reason. However, if it is required that the data needs to be altered either to carry some additional information at some later point, like annotation on images, or correction of errors of omission or commission, etc., it must be done on a copy of the original data, keeping the original data intact, and marking the updated version as active while marking the previous version inactive. The modified data will become part of the EHR/EMR.

Informed Format Change:

318

HEALTH RECORD IT STANDARDS

Whenever, the data, its format or its nature needs to be changed within the system, it must be done with the explicit consent of the doctor / technician / person that is entering or managing the data. This explicit consent can also be taken from a set of preferences already set by the user or the administrator / root of the system. In such preference based consent, there is no need to prompt the user for permission at each insertion point.

Also, in case the system is set to change format or nature of data automatically by setting of preferences, it must be made sure that the rule of conversion is declared in the Standard Operating Procedure (SOP) of site/application.

317

Guidelines

HARDWARE

- The IT hardware used should meet (and preferably be better than) the optimal requirements specified by the software (to be) used.
- The medical and IT hardware used must meet the relevant applicable specifications from BIS, NEMA, IEEE, ISO, CE, RoHS, EnergyStar, apart from Medical and IT standards for the equipment.
- A backup or data preservation mechanism should be considered. Data capacity should be planned to meet the storage requirement as per the mandated rule/law.
- System redundancy at various levels (disk, power, network, etc.) should be planned to meet the organizational system availability requirement.
- Network and data security should be planned, implemented, and periodically audited. Please see section on Security and Privacy for the various requirements and functions that need to be supported and implemented.
- Hardware should be checked periodically for correctness and completeness of operation expected from them. An appropriate maintenance cycle should be planned and rigorously followed.
- Planned and expected Capacity and Quality requirement of the organization should be met by the hardware used. Periodic updates and upgrades should be carried out to meet the requirements.

NETWORKING AND CONNECTIVITY

- Should be able to harness any telecommunications-related connectivity like the Internet, LAN, WAN, WAP, CDMA, GSM or even Cloud Computing that will permit the various EMRs of an individual to be integrated into a single lifelong electronic health record
- As far as is practical and affordable, the connectivity medium chosen should be reliable and fast enough to sustain a secure data exchange for the period expected for transaction of records and data. The speed of the connectivity medium should be chosen from among available options so as to provide an acceptable user experience and not cause software/system fault due to delays/noise/failure.
- Should be able to ensure that data exchange is performed in a secure manner to ensure data validity and non-repudiability
- The data exchange must further ensure that data integrity is maintained at all times

SOFTWARE STANDARDS

The software for capturing, storing, retrieving, viewing, and analyzing healthcare records should:

- Conform to the specified standards
- Satisfy specified requirements
- Be Interoperable, especially in terms of syntax and semantics of the information being exchanged

316

GUIDELINES

- Should be able to ensure user authentication and authorization
- Should be able to support privacy, secrecy and audit trail
- Possess advanced search, merge, and demerge functionality to ensure that duplicates are robustly resolved
- Should be able to support conception-to-current/most recent medical records of a person (as relevant to scope of application)
- Should be able to support digital archiving and retrieval of medical records after the death of a person for the total duration as specified by Government of India from time to time
- Should be able to construct a medical/clinical summary based on available records from the very first visit to current/most recent
- Preferably be able to support rapid data capture-storage-retrieval-display of data

HEALTH RECORD IN MOBILE DEVICES

As people become more mobile and travel becomes more accessible, patients will increasingly expect the healthcare record system to provide essential health information over mobile devices, which will give their treating clinician basic information like, medical condition, drug/allergy information etc. Demographics, insurance info, medications, allergy and alerts, and vital signs are some of the records that are recommended to be provided in at least read-only manner and to the extent relevant for emergency care and quick reference. It is also possible that certain clinical (BP, temperature, glucose count) and lifestyle (steps walked, distance run, sleep duration and quality) related information will additionally be provided by the patient thereby providing vital clues and information on the overall wellbeing of patient.

In the specific regard of design and usability of such applications, m-governance guidelines of DeitY, Ministry of Communication & Information Technology, Government of India shall be applicable. (http://www.deity.gov.in/content/framework-mobile-governance).

315

Data Ownership of Health Records

THE ETHICAL, LEGAL, SOCIAL ISSUES (ELSI) GUIDELINES

For the purposes of these recommendations, the term "privacy" shall mean that only those person or person(s) including organizations duly authorized by the patient may view the recorded data or part thereof. The term "security" shall mean that all recorded personally identifiable data will at all times be protected from any unauthorized access, particularly during transport (e.g. from healthcare provider to provider, healthcare provider to patient, etc.). The term "trust" shall mean that person, persons or organizations (doctors, hospitals, and patients) are those who they claim they are.

The following approaches are to be adopted wherever applicable to address the aspects that the terms mentioned above refer to:

- Privacy would refer to authorization by the owner of the data (the patient)
- Security would have as components both public and private key encryption; the encryption techniques used in transit and at rest need to be through different methodologies.
- Trust would be accepted whenever a trusted third party confirms identity

PROTECTED HEALTH INFORMATION

Protected Health Information (PHI) would refer to any individually identifiable information whether oral or recorded in any form or medium that (1) is created, or received by a stakeholder; and (2) relates to past, present, or future physical or mental health conditions of an individual; the provision of health care to the individual; or past, present, or future payment for health care to an individual.

Electronic Protected Health Information (ePHI) would refer to any protected health information (PHI) that is created, stored, transmitted, or received electronically. Electronic protected health information includes any medium used to store, transmit, or receive PHI electronically.

As per the Information Technology Act 2000, Data Privacy Rules, refer to 'sensitive personal data or information' (Sensitive Data) as the subject of protection, but also refer, with respect to certain obligations, to 'personal information'. Sensitive Data is defined as a subset of 'personal information'. Sensitive Data is defined as personal information that relates to:

1. Passwords
2. Financial information such as bank account or credit card or debit card or other payment instrument details
3. Physical, psychological and mental health condition
4. Sexual orientation
5. Medical records and history
6. Biometric information
7. Any detail relating to (1) – (6) above received by the body corporate for provision of services

314

DATA OWNERSHIP OF HEALTH RECORDS

8. Any information relating to (1) – (7) that is received, stored or processed by the body corporate under a lawful contract or otherwise

DATA OWNERSHIP

- The physical or electronic records, which are generated by the healthcare provider, are held in trust by them on behalf of the patient
- The contained data which are the sensitive personal data of the patient is owned by the patient herself.
- The medium of storage or transmission of such electronic medical record will be owned by the healthcare provider.
- The "sensitive personal information (SPI) and personal information (PI)" of the patient is owned by the patient themselves. Refer to IT Act 2000 for the definition of SPI and PI.

DATA ACCESS AND CONFIDENTIALITY

- Regulations are to be enforced to ensure confidentiality of the recorded patient/medical data and the patient should have a control over this.
- Patients will have the sufficient privileges to inspect and view their medical records without any time limit. Patient's privileges to amend data shall be limited to correction of errors in the recorded patient/medical details. This shall need to be performed through a recorded request made to the healthcare provider within a period of 30 days from the date of discharge in all inpatient care settings or 30 days from the date of clinical encounter in outpatient care settings. An audit of all such changes shall be strictly maintained. Both the request and audit trail records shall be maintained within the system.
- Patients will have the privileges to restrict access to and disclosure of individually identifiable health information and need to provide explicit consent, which will be audited, to allow access and/or disclosures.
- All recorded data will be available to care providers on an 'as required on demand' basis

DISCLOSURE OF PROTECTED / SENSITIVE INFORMATION

- For use in treatment, payments and other healthcare operations: In all such cases, a general consent must be taken from the patient or next of kin, etc. as defined by applicable laws by MCI.
- Fair use for non-routine and most non-health care purposes: a specific consent must be taken from the patient; format as defined by MCI.
- For certain specified national priority activities, including notifiable/communicable diseases, the health information may be disclosed to appropriate authority as mandated by law without the patient's prior authorization
- Instances where use and disclosure without individual authorization will be possible are as follows:
    - Complete record with all identifiers in an "as-is" state, on production of court order

DATA OWNERSHIP OF HEALTH RECORDS

  - Totally anonymized data, where the anonymization process involves the complete removal of all information that allows the identification of the patient. (List of such personally identifiable information is provided below)

RESPONSIBILITIES OF A HEALTHCARE PROVIDER

- Protect and secure the stored health information, as per the guidelines specified in this document
- While providing patient information, remove patient identifying information (as provided in the list below), if it is not necessary to be provided
- Will ensure that there are appropriate means of informing the patient of policies relating to her/his rights to health record privacy
- Document all its privacy policies and ensure that they are implemented and followed. This will include:
  - Develop internal privacy policies
  - Designate a privacy officer (preferably external, may be internal) who will be responsible for implementing privacy policies, audit and quality assurance
  - Provide privacy training to all its staff

PRIVILEGES OF PATIENT OR PERSONAL REPRESENTATIVE

Patient will have the privilege to appoint a personal representative to carry out the activities detailed below.

- Patients will have the privilege to ask for a copy of its medical records held by a healthcare organization.
- Patients will have the privilege to request a healthcare organization that stores/maintains his/her medical records, to withhold specific information that he/she does not want disclosed to other organizations or individuals.
- Patient can demand information from a healthcare provider on the details of disclosures performed on the patient's medical records for any reason whatsoever

DENIAL OF INFORMATION

Healthcare provider will be able to deny information to a patient or representative or third party, in contravention of normal regulations, if in the opinion of a licensed healthcare professional the release of information would endanger the life or safety of the patients and others. This will include but not be limited to as follows:

- Information obtained from an anonymous source under a promise of confidentiality.
- Psychotherapy notes.
- Information compiled for civil, criminal or administrative action.

DATA OWNERSHIP OF HEALTH RECORDS

ELECTRONIC MEDICAL RECORDS PRESERVATION

Preservation of medical records assume significant importance in view of the fact that an electronic health record of a person is an aggregation of all electronic medical records of the person from the very first entry till date. Hence, all records must compulsorily be preserved and not destroyed during the life-time of the person, ever.

Upon the demise of the patient where there are no court cases pending, the records can be removed from active status and turned to inactive status. ISVs are free to decide when to make a record inactive, however, it is preferable to follow the "three (3) year rule" where all records of a deceased are made inactive three (3) years after death.

It is however preferred and ISVs are strongly encouraged to ensure that the records are never be destroyed or removed permanently. The health of the blood relatives and natural descendants of the person can be strongly influenced by the health of the person and on-demand access to these may prove to be hugely useful in the maintenance of the health of the relations.

Furthermore, analysis of health data of all persons is expected to greatly benefit in the understanding of health, disease processes and the amelioration thereof.

With rapid decline in costs of data archiving coupled with the ability to store increasing amounts of data that may be readily accessible, continued maintenance of such data is not expected to lead to any major impact on the overall system maintenance and use.

PATIENT IDENTIFYING INFORMATION

Data are "individually identifiable" if they include any of the under mentioned identifiers for an individual or for the individual's employer or family member, or if the provider or researcher is aware that the information could be used, either alone or in combination with other information, to identify an individual These identifiers are as follows:

- Name
- Address (all geographic subdivisions smaller than street address, and PIN code)
- All elements (except years) of dates related to an individual (including date of birth, date of death, etc.)
- Telephone, cell (mobile) phone and/or Fax numbers
- Email address
- Bank Account and/or Credit Card Number
- Medical record number
- Health plan beneficiary number
- Certificate/license number
- Any vehicle or other any other device identifier or serial numbers
- PAN number
- Passport number

DATA OWNERSHIP OF HEALTH RECORDS

- AADHAAR card
- Voter ID card
- Fingerprints/Biometrics
- Voice recordings that are non-clinical in nature
- Photographic images and that possibly can individually identify the person
- Any other unique identifying number, characteristic, or code

APPLICABLE LEGISLATION

The existing Indian laws including IT Act 2000 and their amendments from time to time would prevail (http://deity.gov.in/content/information-technology-act-2000).

DATA PRIVACY AND SECURITY

Data Privacy and Security

SECURITY OF ELECTRONIC HEALTH INFORMATION:

The Privacy Standards and the Security Standards are necessarily linked. Any health record system requires safeguards to ensure that the data is available when needed and that information is not used, disclosed, accessed, altered, or deleted inappropriately while being stored or retrieved or transmitted. The Security Standards work together with the Privacy Standards to establish appropriate controls and protections. Health sector entities that are required to comply with the Privacy Standards also must comply with the Security Standards.

Organizations must consider several factors when adopting security measures. How a healthcare provider satisfies the security requirements and which technology it decides to use are business decisions left to the individual organizations. In deciding what security measures to adopt, an organization must consider its size, complexity, and capabilities; it's technical infrastructure, hardware, and software security capabilities; the cost of particular security measures; and the probability and degree of the potential risks to the ePHI it stores, retrieves and transmits.

PURPOSE OF THE SECURITY STANDARDS

The security standards require healthcare providers to implement reasonable and appropriate *administrative*, *physical*, and *technical* safeguards to:

- ensure the confidentiality, integrity, and availability of all the e-PHI they create, transmit, receive, or maintain
- protect against reasonably anticipated threats or hazards to the security or integrity of their e-PHI
- protect against uses or disclosures of the e-PHI that are not required or permitted under the Privacy Standards
- ensure their workforce will comply with their security policies and procedures

TECHNICAL STANDARDS

To protect the ePHI handles by a healthcare provider, the provider must implement technical safeguards as part of its security plan. Technical safeguards refer to using technology to protect ePHI by controlling access to it. Therefore, they must address the following standards focusing on the following functionalities. It is worth noting that they will need to use an EHR/EMR solution that is able to successfully and robustly demonstrate the possession and working of these functionalities.

The basic requirements for security and privacy are provided in following standard:

1. ISO/TS 14441:2013 Health Informatics – Security & Privacy Requirements of EHR Systems for Use in Conformity Assessment

309

Authentication:

- Locally within the system the fact that a person or entity seeking access to electronic health information is indeed the one as claimed and is also authorized to access such information must be verifiable.
- Across the network, however extensive it might be, the fact that a person or entity seeking access to electronic health information across a network is the one claimed and is authorized to access such information in accordance with the standard specified in this document must be verifiable.

Automatic log-off: An electronic session after a predetermined time of inactivity must be forcibly terminated. To log in back, the user will have to initiate a new log in session. However, for the sake of ergonomics, it is recommended that the unsaved state of the system at the time of automatic log-off be saved and presented back to the user for further action. This should be a user-specific feature.

The advisory standard for overall information security management in health is:

2. ISO 27799 Health informatics - Information Security Management in Health using ISO/IEC 27002

Implementation Guideline: The ISO 27799 is provided as a basic advisory standard for security management. Other security management and standard / practices / guidelines given by Law (such as IT Act 2000 and amendments) or regulatory / statutory / certification bodies (such as National Accreditation Board for Hospitals & Health care Providers (NABH)) should be taken in consideration when designing and/or implementing health record system.

Access control: The solution must assign a unique name and/or number for identifying and tracking user identity and establish controls that permit only authorized users to access electronic health information. In cases of emergency where access controls need to be suspended in order to save a live, authorized users (who are authorized for emergency situations) will be permitted to have unfettered access electronic health information for the duration of the emergency with the access remaining in force during the validity of the emergency situation.

Access Privileges: Ideally only clinical care providers should have access rights to a person's clinical records. However, different institutional care providers have widely varying access privileges specified that are institution-specific. No country-wide standards can be specified for this at least at this point in time.

For privilege management and access control, following standards may be used:

3. ISO 22600:2014 Health informatics - Privilege Management and Access Control (Part 1 through 3)

Implementation Guideline: The ISO 22600 set of standards is provided as an advisory standard for policy based access control. For the purpose of privilege management, rule / policy based access is expected to give better control and flexibility in defining and enforcing access control. Access control mechanisms such

308

as Role Based, Policy Based, or singular user (applicable in case of mobile based PHR) are acceptable as long as conformant to applicable data security law(s) and rules as well as policy of the organization where implemented.

Audit log:

- All actions related to electronic health information in accordance with the standard specified in this document including viewing should be recorded.
- Based on user-defined events must be provided.
- All or a specified set of recorded information upon request or at a set period of time must be electronically displayed and printed.

The advisory standard for audit trail / log in health record system is:

4. ISO 27789:2013 Health informatics - Audit Trails for Electronic Health Records

Integrity:

- During data transit the fact that the electronic health information has not been altered in transit in accordance with the standard specified in this document must be verifiable.
- Detection of events – all alterations and deletions of electronic health information and audit logs, in accordance with the standard specified in this document must be detected.
- Appropriate verification that electronic health information has not been altered in transit shall be possible at any point in time. A secure hashing algorithm must be used to verify that electronic health information has not been altered in transit and it is recommended that the Secure Hash Algorithm (SHA) used must be SHA-256 or higher.

Encryption:

- Generally, all electronic health information must be encrypted and decrypted as necessary according to organization defined preferences in accordance with the best available encryption key strength (minimum 256-bits key).
- During data exchange all electronic health information must be suitably encrypted and decrypted when exchanged in accordance with an encrypted and integrity protected link.
- All actions related to electronic health information must be recorded with the date, time, patient identification, and user identification whenever any electronic health information is created, modified (non-clinical data only), deleted (stale and non-clinical data only), or printed; and an indication of which action(s) took place must also be recorded.

- A cross-enterprise secure transaction that contains sufficient identity information such that the receiver can make access control decisions and produce detailed and accurate security audit trails must be used within the system.
- Secure Transmission standards and mechanisms must be used to allow access to health information as well as transmit data from one application / site to another. For this purpose HTTPS, SSL v3.0, and TLS v1.2 standards should be used. Please refer to relevant IETF, IEEE, ISO, and FIPS standards for same.

Digital Certificates:

Use of Digital Certificates for identification and digital signing is recommended in health record system. Health record system must use following standard where digital certificates are used:

5. ISO 17090 Health informatics - Public Key Infrastructure (Part 1 through 5)

ADMINISTRATIVE SAFEGUARDS STANDARDS

The Administrative Safeguards require healthcare providers to develop and implement a security management process that includes policies and procedures that address the full range of their security vulnerabilities. Being administrative in nature, these need to be internally designed and developed as standard operating procedure (SOP) that must be published for all users to see and adhere to. Conformance to adherence may be delegated to the Privacy Officer detailed in the Data Ownership chapter above. To comply with the Administrative Safeguards, a healthcare provider must implement the following standards.

- The security management process standard, to prevent security violations;
- Assigned security responsibility, to identify a security officer;
- Workforce security, to determine e-PHI user access privileges;
- Information access management, to authorize access to e-PHI;
- Security awareness training, to train staff members in security awareness;
- Security incident procedures, to handle security incidents;
- Contingency plan, to protect e-PHI during an unexpected event; and
- Evaluation, to evaluate an organization's security safeguards.

PHYSICAL SAFEGUARDS STANDARDS

Physical safeguards are security measures to protect a healthcare provider's electronic information systems, related equipment, and the buildings housing the systems from natural and environmental hazards, and unauthorized intrusion. Healthcare providers must fulfill the following four standards. However, since most of the implementation specifications in this category are addressable, healthcare providers have flexibility in determining how to comply with the requirements as long as these are internally designed and developed as per the relevant SOP and published for all users to see and adhere to. Conformance to adherence may be delegated to the Privacy Officer detailed in the Data Ownership chapter above.

The required physical standards are:

- The facility access control standard, to limit actual physical access to electronic information systems and the facilities where they're located;
- The workstation use standard, to control the physical attributes of a specific workstation or group of workstations, to maximize security;
- The workstation security standard, to implement physical safeguards to deter the unauthorized access of a workstation; and
- The device and media controls standard, to control the movement of any electronic media containing ePHI from, to or within the facility.

Glossary

The various terms, including acronyms, are explained from a conceptual point and may not be the formal definitions.

ADSL (Asymmetric Digital Subscriber Line): A type of DSL that uses copper telephone lines to transmit data faster than a traditional modem. ADSL only works within short distances because it uses high frequencies with short signals.

Allergy List: This is a list of all the patient's allergies.

Allopathic, Allopathy: Defined as relating to or being a system of medicine that aims to combat disease by using remedies (as drugs or surgery) which produce effects that are different from or incompatible with those of the disease being treated

Ambulatory care: Any medical care delivered on an outpatient basis.

ANM: Auxiliary Nurse Midwife

Archetype: Basically an information model, it is a computable expression of a domain content model in the form of structured constraint statements, based on a reference (information) model. Within the openEHR paradigm, archetypes are based on the openEHR reference model. Archetypes are all expressed in the same formalism. In general, they are defined for wide re-use, however, they can be specialized to include local particularities. They can accommodate any number of natural languages and terminologies.

Artefact: An object made by a human being, typically one of cultural or historical interest. In healthcare IT context, an artefact is any item such as a document, file or drawing, etc. that is generated for use as a reference material or inside a system.

ASHA: Accredited Social Health Activist is usually a literate 25 – 45 year old married/ widowed/ divorced lady selected from the village itself and accountable to it and trained to work as an interface between the community and the public health system. This is position is one of the key components of the National Rural Health Mission aimed at providing every village in the country with a trained female community health activist

ATC: Anatomical Therapeutic Chemical Classification System, controlled by the WHO Collaborating Centre for Drug Statistics Methodology (WHOCC), is used for drug classification.

Authentication: The verification of the identity of a person or process.

Authorization: Any document designating any permission. Authorization or waiver of authorization for the use or disclosure of identifiable health information for research (among other activities) is required. The authorization must indicate if the health information used or disclosed is existing information and/or new information that will be created. The authorization form may be combined with the informed consent form, so that a patient need sign only one form. An authorization must include the following specific elements: a

description of what information will be used and disclosed and for what purposes; a description of any information that will not be disclosed, if applicable; a list of who will disclose the information and to whom it will be disclosed; an expiration date for the disclosure; a statement that the authorization can be revoked; a statement that disclosed information may be re-disclosed and no longer protected; a statement that if the individual does not provide an authorization, she/he may not be able to receive the intended treatment; the subject's signature and date.

AYUSH: Ayurveda, Yoga, Unani, Siddha and Homeopathy. Falls under the broad category of Indian Systems of Medicines and Homoeopathy (ISM&H) governed by Ministry of Health and Family Welfare, Government of India

[C]

CCD (Continuity of Care Document): A joint effort of HL7 International and ASTM. CCD fosters interoperability of clinical data by allowing physicians to send electronic medical information to other providers without loss of meaning and enabling improvement of patient care. CCD is an implementation guide for sharing Continuity of Care Record (CCR) patient summary data using the HL7 Version 3 Clinical Document Architecture (CDA), Release 2. It establishes a rich set of templates representing the typical sections of a summary record, and these same templates for vital signs, family history, plan of care, and so on can then be used for establishing interoperability across a wide range of clinical use cases.

CDT: Common Dental Terminology

Chain of Trust Agreement: A contract needed to extend the responsibility to protect health care data across a series of sub-contractual relationships.

Chief Complaint (CC), Reason for Consultation (RFC), Reason of Visit (ROV): for recording a patient's disease symptoms.

Client/Server Architecture: An information-transmission arrangement, in which a client program sends a request to a server. When the server receives the request, it disconnects from the client and processes the request. When the request is processed, the server reconnects to the client program and the information is transferred to the client. This usually implies that the server is located on site as opposed to the ASP (Application Server Provider) architecture.

Clinical Care Provider: Personnel or entities directly related to providing clinical care to patient.

Clinical Data Repository (CDR): A real-time database that consolidates data from a variety of clinical sources to present a unified view of a single patient. It is optimized to allow clinicians to retrieve data for a single patient rather than to identify a population of patients with common characteristics or to facilitate the management of a specific clinical department.

Clinical Decision Support System (CDSS): A clinical decision support system (CDSS) is software designed to aid clinicians in decision making by matching individual patient characteristics to computerized knowledge bases for the purpose of generating patient-specific assessments or recommendations.

303

GLOSSARY

Clinical Establishment: Clinical establishment means (1) a hospital, maternity home, nursing home, dispensary, clinic, sanatorium or an institution by whatever name called that offers services, facilities requiring diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognized system of medicine established and administered or maintained by any person or body of persons, whether incorporated or not; or (2) a place established as an independent entity or part of an establishment referred to above, in connection with the diagnosis or treatment of diseases where pathological, bacteriological, genetic, radiological, chemical, biological investigations or other diagnostic or investigative services with the aid of laboratory or other medical equipment, are usually carried on, established and administered or maintained by any person or body of persons, whether incorporated or not. (Clinical Establishment Act – CEA 2010)

Clinical Guidelines (Protocols): Clinical guidelines are recommendations based on the latest available evidence for the appropriate treatment and care of a patient's condition.

Clinical Messaging: Communication of clinical information within the electronic medical record to other healthcare personnel.

Coded Data: Data are separated from personal identifiers through use of a code. As long as a link exists, data are considered indirectly identifiable and not anonymous or anonymized.

Code Set: Any set of codes used to encode data elements, such as tables of terms, medical concepts, medical diagnostic codes, or medical procedure codes. This includes both the codes and their descriptions.

Coding: A mechanism for identifying and defining physicians' and hospitals' services. Coding provides universal definition and recognition of diagnoses, procedures and level of care. Coders usually work in medical records departments and coding is a function of billing. Medicare fraud investigators look closely at the medical record documentation, which supports codes and looks for consistency. Lack of consistency of documentation can earmark a record as "up-coded" which is considered fraud. A national certification exists for coding professionals and many compliance programs are raising standards of quality for their coding procedures.

Computer-Based Patient Record (CPR): A term for the process of replacing the traditional paper-based chart through automated electronic means; generally includes the collection of patient-specific information from various supplemental treatment systems, i.e., a day program and a personal care provider; its display in graphical format; and its storage for individual and aggregate purposes. CPR is also called "digital medical record" or "electronic medical record".

Computerized Patient Record (CPR): Also known as an EMR or EHR.A patient's past, present, and future clinical data stored in a server.

Computerized Physician Order Entry (CPOE): A system for physicians to electronically order labs, imaging and prescriptions

302

GLOSSARY

CPT (Current Procedural Terminology) Code: A recognizable five-digit number used to represent a service provided by a healthcare provider. It is a manual that assigns five digit codes to medical services and procedures to standardize claims processing and data analysis. The coding system for physicians' services developed by the CPT Editorial Panel of the American Medical Association.

[D]

Data Content: All the data elements and code sets inherent to a transaction, and not related to the format of the transaction.

Data: This is factual information (as measurements or statistics) used as a basis for reasoning, discussion, or calculation. It additionally points to the information output by a sensing device or organ that includes both useful and irrelevant or redundant information and must be processed to be meaningful.

Database Management System (DBMS): The separation of data from the computer application that allows entry or editing of data.

DICOM (Digital Imaging and Communications in Medicine): Digital Imaging and Communications in Medicine (DICOM) is a standard to define the connectivity and communication between medical imaging devices.

Disease Management: A type of product or service now being offered by many large pharmaceutical companies to get them into broader healthcare services. Bundles use of prescription drugs with physician and allied professionals, linked to large databases created by the pharmaceutical companies, to treat people with specific diseases. The claim is that this type of service provides higher quality of care at more reasonable price than alternative, presumably more fragmented, care. The development of such products by hugely capitalized companies should be the entire indicator necessary to convince a provider of how the healthcare market is changing. Competition is coming from every direction—other providers of all types, payers, employers who are developing their own in-house service systems, the drug companies.

Document Imaging: Is a process of converting paper documents into an electronic format usually through a scanning process.

Document Management: The Document Manager allows the medical institution to store vital patient documents such as X-Ray's, Paper Reports, and Lab Reports etc.

Documentation: The process of recording information.

DOHAD: Developmental Origins of Health and Diseases

Drug Formulary: Varying lists of prescription drugs approved by a given health plan for distribution to a covered person through specific pharmacies. Health plans often restrict or limit the type and number of medicines allowed for reimbursement by limiting the drug formulary list. The list of prescription drugs for which a particular employer or State Medicaid program will pay. Formularies are either "closed," including

301

only certain drugs or "open," including all drugs. Both types of formularies typically impose a cost scale requiring consumers to pay more for certain brands or types of drugs. See also Formulary.

Drug Formulary Database: This EMR feature is used for electronic prescribing, electronic medical record (EMR), and computerized physician order entry (CPOE) systems to present formulary status to the provider while during the prescribing decision.

DSM: Diagnostic and Statistical Manual for Mental Diseases

[E]

EDI: Acronym for Electronic Data Interchange. Electronic communication between two parties, generally for the filing of electronic claims to payers.

EDI Translator: Used in electronic claims and medical record transmissions, this is a software tool for accepting an EDI transmission and converting the data into another format, or for converting a non-EDI data file into an EDI format for transmission. See also Electronic Data Interchange.

EHR/EMR System Designer, Developer, Manufacturer, Vendor, Supplier, Retailer, Re-seller: Any entity that is involved in the design, development, testing, manufacturing, supplying, selling including re-selling of Electronic Health Records or Electronic Medical Records Systems as a whole or part thereof.

Electronic Data Interchange (EDI): The automated exchange of data and documents in a standardized format. In health care, some common uses of this technology include claims submission and payment, eligibility, and referral authorization. This refers to the exchange of routine business transactions from one computer to another in a standard format, using standard communications protocols.

Electronic Health Records (EHR): The one or more repositories, physically or virtually integrated, of information in computer processable form, relevant to the wellness, health and healthcare of an individual, capable of being stored and communicated securely and of being accessible by multiple authorized users, represented according to a standardized or commonly agreed logical information model. Its primary purpose is the support of life-long, effective, high quality and safe integrated healthcare. [ISO 18308:2011]

Electronic Medical Records (EMR): The EMR could be considered as special case of the EHR, restricted in scope to the medical domain or at least very much medically focused [ISO/TR 20514]. The Japanese Association of Healthcare Information Systems (JAHIS) has defined a five-level hierarchy of the EMR; Departmental EMR: contains a patient's medical information entered by a single hospital department (e.g. pathology, radiology, pharmacy); Inter-departmental EMR: contains a patient's medical information from two or more hospital departments; Hospital EMR: contains a patient's clinical information from a particular hospital; Inter-hospital EMR: contains a patient's medical information from two or more hospitals; EHR: longitudinal collection of health information from all sources. [Classification of EMR systems, JAHIS, V1.1, Mar 1996]

Electronic Protected Health Information (ePHI): Electronic Protected Health Information (ePHI) is any protected health information (PHI) that is created, stored, transmitted, or received electronically. Electronic

protected health information includes any medium used to store, transmit, or receive PHI electronically. The following and any future technologies used for accessing, transmitting, or receiving PHI electronically are covered. Media containing data at rest (data storage) like personal computers with internal hard drives used at work, home, or traveling, external portable hard drives, including iPods and similar devices, magnetic tape, removable storage devices, such as USB memory sticks, CDs, DVDs, and floppy disks, PDAs and smartphones and data in transit, via wireless, Ethernet, modem, DSL, or cable network connections, Email, File transfer. (For Protected Health Information – PHI, please see below)

Encounter: A clinical encounter is defined by ASTM as "(1) an instance of direct provider/practitioner to patient interaction, regardless of the setting, between a patient and a practitioner vested with primary responsibility for diagnosing, evaluating or treating the patient's condition, or both, or providing social worker services. (2) A contact between a patient and a practitioner who has primary responsibility for assessing and treating the patient at a given contact, exercising independent judgment." Encounter serves as a focal point linking clinical, administrative and financial information. Encounters occur in many different settings -- ambulatory care, inpatient care, emergency care, home health care, field and virtual (telemedicine). [http://www.ncvhs.hhs.gov/040127p1.htm]

Episode: An episode of care consists of all clinically related services for one patient for a discrete diagnostic condition from the onset of symptoms until the treatment is complete [http://www.ncmedsoc.org/non_members/pai/PAI-FinalWorkbookforVideo.pdf] Thus, for every new problem or set of problems that a person visits his clinical care provider, it is considered a new episode. Within that episode the patient will have one or many encounters with his clinical care providers till the treatment for that episode is complete. Even before the resolution of an episode, the person may have a new episode that is considered as a distinctly separate event altogether. Thus, there may be none, one or several ongoing active episodes. All resolved episodes are considered inactive. Hence they become part of the patient's past history. A notable point here is that all chronic diseases are considered active and may never get resolved during the life-time of the person, e.g., diabetes mellitus, hypertension, etc.

EPR: Broadly defined, a personal health record is the documentation of any form of patient information–including medical history, medicines, allergies, visit history, or vaccinations–that patients themselves may view, carry, amend, annotate, or maintain. Today, when we refer to PHRs, we typically mean an online personal health record–which may variously be referred to as an ePHR, an Internet PHR, an Internet medical record, or a consumer Internet Medical Record (CIMR). Generally, such records are maintained in a secure and confidential environment, allowing only the individual, or people authorized by the individual, to access the medical information. Not all electronic PHRs are Internet PHRs. PC-based PHRs may be set up to capture medical information offline.

Evidence Based Medicine: Evidence-based medicine (EBM) is the integration of best research evidence with clinical expertise to aid in the diagnosis and management of patients.

[F]

299

Family History: A list of the patient's family medical history including the chronic medical problems of parents, siblings, grandparents, etc.

FHIR: Fast Health Interoperable Resources, the newest version from HL7 org for messaging.

Formatting and Protocol Standards: Data exchange standards which are needed between CPR systems, as well as CPT and other provider systems, to ensure uniformity in methods for data collection, data storage and data presentation. Proactive providers are current in their knowledge of these standards and work to ensure their information systems conform to the standards.

Formulary: An approved list of prescription drugs; a list of selected pharmaceuticals and their appropriate dosages felt to be the most useful and cost effective for patient care. Organizations often develop a formulary under the aegis of a pharmacy and therapeutics committee. In HMOs, physicians are often required to prescribe from the formulary. See also Drug Formulary.

[G]

Growth Chart: A feature for a Primary Care or EMR that can be used for pediatric patients. Age, height, weight, and head measurements can be entered over the patient's lifetime, and the feature creates a line graph.

[H]

Health Care Operations: Institutional activities that is necessary to maintain and monitor the operations of the institution. Examples include but are not limited to: conducting quality assessment and improvement activities; developing clinical guidelines; case management; reviewing the competence or qualifications of health care professionals; education and training of students, trainees and practitioners; fraud and abuse programs; business planning and management; and customer service. Under the HIPAA Privacy Rule, these are allowable uses and disclosures of identifiable information "without specific authorization." Research is not considered part of health care operations.

Health Care, Healthcare: Care, services, and supplies related to the health of an individual. Health care includes preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, among other services. Healthcare also includes the sale and dispensing of prescription drugs or devices.

Health Information: Information in any form (oral, written or otherwise) that relates to the past, present or future physical or mental health of an individual. That information could be created or received by a health care provider, a health plan, a public health authority, an employer, a life insurer, a school, a university or a health care clearinghouse. All health information is protected by state and federal confidentiality laws and by HIPAA privacy rules.

Health Level Seven (HL7): A data interchange protocol for health care computer applications that simplifies the ability of different vendor-supplied IS systems to interconnect. Although not a software program in itself, HL7 requires that each healthcare software vendor program HL7 interfaces for its products. The organization is one of the American National Standards Institute accredited Standard Developing

298

Organization (SDO) - Health Level 7 domain is the standards for electronic interchange of clinical, financial and administrative info among healthcare oriented computer systems. Is a not-for-profit volunteer organization. It develops specifications, most widely used is the messaging standard that enables disparate health care applications to exchange key sets of clinical and administrative data. It promotes the use of standards within and among healthcare organizations to increase the effectiveness and efficiency of healthcare delivery. It is an international community of healthcare subject matter experts and information scientists collaborating to create standards for the exchange, management and integration of electronic healthcare information.

Health: The state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity. It is recognized, however, that health has many dimensions (anatomical, physiological, and mental) and is largely culturally defined. The relative importance of various disabilities will differ depending upon the cultural milieu and the role of the affected individual in that culture. Most attempts at measurement have been assessed in terms or morbidity and mortality.

Healthcare provider: A health care provider is an individual or an institution that provides preventive, curative, promotional or rehabilitative health care services in a systematic way to individuals, families or communities. An individual health care provider may be a health care professional, an allied health professional, a community health worker, any or other person trained and knowledgeable in medicine, nursing or other allied health professions, or public/community health workers like , ASHA, ANM, midwives, paramedical staff, OT/lab/radio-diagnostic technicians, etc. An institution will include hospitals, clinics, primary care centers and other service delivery points of health care individual clinics, polyclinics, diagnostic centers, etc., i.e., any place where a medical record is generated during a patient-care provider encounter (in conformance to CEA 2010 – please refer to Clinical Establishment item above). It must be noted that any person solely performing non-clinical work is not a care provider.

Healthcare Service Provider (HSP): see Healthcare provider

History of Present Illness (HPI): The HPI is the history of the patient's chief complaint.

Human Subject: Refers to a living subject participating in research about whom directly or indirectly identifiable health information or data are obtained or created.

Hybrid Record: Term used for when a provider uses a combination of paper and electronic medical records during the transition phase to EMR.

[I]

Independent Software Vendor (ISV): A company specializing in making or selling software products that runs on one or more computer hardware or operating system platforms.

Immunization: A complete list of all immunizations that the patient has had.

Informatics: The application of computer technology to the management of information.

297

Integration: Integration allows for secure communication between enterprise applications.

Interface: A means of communication between two computer systems, two software applications or two modules. Real time interface is a key element in healthcare information systems due to the need to access patient care information and financial information instantaneously and comprehensively. Such real time communication is the key to managing health care in a cost effective manner because it provides the necessary decision-making information for clinicians, providers, other stakeholders, etc.

International Classification of Diseases: This is the universal coding method used to document the incidence of disease, injury, mortality and illness. A diagnosis and procedure classification system designed to facilitate collection of uniform and comparable health information. The ICD-9-CM was issued in 1979. This system is used to group patients into DRGs, prepare hospital and physician billings and prepare cost reports. Classification of disease by diagnosis codified into six-digit numbers. See also coding.

International Health Terminology Standards Development Organization (IHTSDO): Denmark-based organization that maintains and licenses SNOMED codes worldwide.

Interoperability: The capability to provide successful communication between end-users across a mixed environment of different domains, networks, facilities and equipment.

ISP: Internet Service Provider

ISV (Independent Software Vendor): An independent software vendor (ISV) is a company specializing in making or selling software, designed for mass or niche markets. This typically applies for application-specific or embedded software, from other software producers.

[J]

J-Codes: A subset of the HCPCS Level II code set with a high-order value of "J" that has been used to identify certain drugs and other items.

[L]

LAN (Local Area Network): A LAN supplies networking capability to a group of computers in close proximity to each other such as in an office building, a school, or a home.

Legacy System Integration: The integration of data between a legacy system and some other software program most commonly using HL-7 standards.

Legacy Systems: Computer applications, both hardware and software, which have been inherited through previous acquisition and installation. Most often, these systems run business applications that are not integrated with each other. Newer systems which stress open design and distributed processing capacity are gradually replacing such systems.

Length of Stay (LOS): The duration of an episode of care for a covered person. The number of days an individual stays in a hospital or inpatient facility. May also be reviewed as Average Length of Stay (ALOS).

GLOSSARY

LEPR (Longitudinal Patient Record): Longitudinal Patient Record is an EHR that includes all healthcare information from all sources.

[M]

Management Information System (MIS): The common term for the computer hardware and software that provides the support of managing the plan.

Master Patient / Member Index: An index or file with a unique identifier for each patient or member that serves as a key to a patient's or member's health record.

Maximum Defined Data Set: All of the required data elements for a particular standard based on a specific implementation specification. An entity creating a transaction is free to include whatever data any receiver might want or need. The recipient is free to ignore any portion of the data that is not needed to conduct their part of the associated business transaction, unless the inessential data is needed for coordination of benefits.

MCI: Medical Council of India

Medical Code Sets: Codes that characterize a medical condition or treatment. These code sets are usually maintained by professional societies and public health organizations. Compare to administrative code sets.

Medical Informatics: Medical informatics is the systematic study, or science, of the identification, collection, storage, communication, retrieval, and analysis of data about medical care services to improve decisions made by physicians and managers of health care organizations. Medical informatics will be as important to physicians and medical managers as the rules of financial accounting are to auditors.

Medical Management Information System (MMIS): A data system that allows payers and purchasers to track health care expenditure and utilization patterns. It may also be referred to as Health Information System (HIS), Health Information Management (HIM) or Information System (IS). See also Electronic Medical Record (EMR).

Metadata and Date Standard (MDDS) – A set of data elements and their specification for use in certain domain, such as health, e-governance.

MIMS: Monthly Index of Medical Specialties

Minimum Data Set: The minimum set of data elements that must be captured, stored, made available for retrieval, presentation, relay and sharing by an EHR system. It comprises of all of the essential data elements required for implementation. An entity creating a transaction must include the mandatory data elements at all times and is free to exclude optional data elements. The entity is free to additionally include whatever other data elements that any receiver might want or need. The recipient is free to ignore any portion of the data that is not mandatory and is further free to ignore any other portion of the data that is not needed to conduct their part of the associated transaction, unless required by sender, intermediaries or receiver. This minimum data set represents the most common data, and system designers are at liberty to add to it as they deem necessary to enrich or enhance their EHR systems.

295

Modifier: Additional character of a code added to an existing code that is used to help in extending or localization of the existing code.

[N]

NANDA: North American Nursing Diagnosis Association

National Council for Prescription Drug Programs: An ANSI-accredited group that maintains a number of standard formats for use by the retail pharmacy industry.

NEMA: The National Electrical Manufacturers Association (NEMA) is the association of electrical equipment and medical imaging manufacturers, founded in 1926 and headquartered in Rosslyn, Virginia.

Non-Participating Physician (or Provider): A provider, doctor or hospital that does not sign a contract to participate in a health plan, usually which requires reduced rates from the provider. In the Medicare Program, this refers to providers who are therefore not obligated to accept assignment on all Medicare claims. In commercial plans, non-participating providers are also called out of network providers or out of plan providers. If a beneficiary receives service from an out of network provider, the health plan (other than Medicare) will pay for the service at a reduced rate or will not pay at all.

[O]

Open Access: A term describing a member's ability to self-refer for specialty care. Open access arrangements allow a member to see a participating provider without a referral from another doctor. Health plan members' abilities, rights or invitation to self refer for specialty care. Also called Open Panel.

openEHR: openEHR is an open standard specification in health informatics that describes the management and storage, retrieval and exchange of health data in electronic health records (EHRs). In openEHR, all health data for a person is stored in a "one lifetime", vendor-independent, person-centered EHR. Maintained by the openEHR Foundation, these are based on a combination of 15 years of European and Australian research and development into EHRs and new paradigms, including what has become known as the archetype methodology for specification of content and include information and service models for the EHR, demographics, clinical workflow and archetypes. They are designed to be the basis of a medico-legally sound, distributed, versioned EHR infrastructure.

OR: Operating Room – synonymous to OT as below

OT: Operation Theatre

OTC: Over the counter (drugs). Refers to those drugs that are available off the shelf without any prescription or advise from a registered medical practitioner

Outcome: A clinical outcome is the "change in the health of an individual, group of people or population which is attributable to an intervention or series of interventions". (Taken from: Frommer, Michael; Rubin, George; Lyle, David (1992)."The NSW Health Outcomes program". New South Wales Public Health Bulletin 3: 135. doi:10.1071/NB92067)

294

GLOSSARY

Outpatient Care: Care given a person who is not bedridden. It is also called ambulatory care. Many surgeries and treatments are now provided on an outpatient basis, while previously they had been considered reason for inpatient hospitalization. Some say this is the fastest growing segment of healthcare

[P]

Participating Physician: A primary care physician in practice in the payer's managed care service area who has entered into a contract.

Past History: A list of a patient's past health problems, surgeries and specialists.

Patient Demographics: All patient's pertinent information such as first and last name, SSN, DOB, insurance, etc.

Patient Portal: A secure web-based system that allows a patient to register for an appointment, schedule an appointment, request prescription refills, send and receive secure patient-physician messages, view lab results, pay their bills electronically, access physician directories.

Patient: A person who is under medical care or treatment

PC Based: A program designed to run on an individual PC. This typically means data is not shared in real time among other PCs (users).

PCP: Primary care physician who often acts as the primary gatekeeper in health plans. That is, often the PCP must approval referrals to specialists. Particularly in HMOs and some PPOs, all members must choose or are assigned a PCP.

PHR: A personal health record or PHR is typically a health record that is initiated and maintained by an individual. An ideal PHR would provide a complete and accurate summary of the health and medical history of an individual by gathering data from many sources and making this information accessible online.

Picture Archive Communication System (PACS): Used by radiology and diagnostic imaging organizations to electronically manage information and images

Practice Parameters, Practice Guidelines: Systematically developed statements to standardize care and to assist in practitioner and patient decisions about the appropriate health care for specific circumstances. Practice guidelines are usually developed through a process that combines scientific evidence of effectiveness with expert opinion. Practice guidelines are also referred to as clinical criteria, protocols, algorithms, review criteria, and guidelines. The American Medical Association defines practice parameters as strategies for patient management, developed to assist physicians in clinical decision-making. Practice parameters may also be referred to as practice options, practice guidelines, practice policies, or practice standards.

Prescription Drug: Drug that the law says can only be obtained by prescription.

293

Primary Care Physician: A "generalist" such as a family practitioner, pediatrician, internist, or obstetrician. In a managed care organization, a primary care physician is accountable for the total health services of enrollees including referrals, procedures and hospitalization. Also see Primary Care Provider.

Primary Care Provider: The provider that serves as the initial interface between the member and the medical care system. The PCP is usually a physician, selected by the member upon enrollment, who is trained in one of the primary care specialties who treats and is responsible for coordinating the treatment of members assigned to his/her plan.

Primary Care: Basic or general health care usually rendered by general practitioners, family practitioners, internists, obstetricians and pediatricians who are often referred to as primary care practitioners or PCPs. Professional and related services administered by an internist, family practitioner, obstetrician-gynecologist or pediatrician in an ambulatory setting, with referral to secondary care specialists, as necessary.

Principal Diagnosis: The medical condition that is ultimately determined to have caused a patient's admission to the hospital. The principal diagnosis is used to assign every patient to a diagnosis related group. This diagnosis may differ from the admitting and major diagnoses.

Privacy Standards: The Privacy standards restrict the use & disclosure of individually identifiable health information. Privacy standard applies to all protected health information may it is in physical or electronic form.

Privacy: Privacy means an individual's interest in limiting who has access to personal health care information. Specific patient authorization is required for use and disclosure of clinical notes. As per Fernando & Dawson, 2009, privacy is control of access to private information avoiding certain kinds of embarrassment and can be shared or not shared with others; Only authorized (by the patient) people can view the recorded data or part thereof

Progress Note: The documentation of a patient visit or encounter including all or part of the SOAP format.

Protected health information (PHI): Any individually identifiable information whether oral or recorded in any form or medium that is created, or received by a health care provider, health plan or health care Healthcare provider and relates to past, present, or future physical or mental health conditions of an individual; the provision of health care to the individual; or past, present, or future payment for health care to an individual.

[R]

Real Time: The instantaneous sharing of data among a user group. It is common to a client/server database configuration.

Reference Model (RM):

Referral: Some insurance companies require that on specific plans a referral must be obtained for certain procedures or visits to specialists. The referral is acquired by the primary care physician (PCP) by

contacting the insurance company by phone or mail. This is a request for the service. The referral consists of an authorization code, a number of visits allowed (if applicable) and an expiration date.

Referring Provider: is the provider that referred the patient to a specialist or for a specific procedure.

Regenstrief: The Regenstrief Institute is an international non-profit medical research organization associated with Indiana University. It produces and maintains LOINC codes.

Relational Database: A database program that stores data in a manner similar to Excel, with the difference being the data elements are related (linked) to each other.

Remote Access: Data travels through a private, protected passage via the Internet, allowing healthcare providers to access from home or another practice location and allows EMR vendor to perform system maintenance off-site

Rendering/Performing Provider: The provider actually treating the patient.

Roles and Access Levels: The role and access level of the user needs to be determined and set by the system administrator. The role determines the access level. While roles may be such as system administrator, medical doctor, registered nurse, medical student, medical assistant, nurse assistant, ancillary nurse, health worker, Anganwadi worker (grass-root health worker), etc., the access levels may include viewing only, viewing/adding/editing only, viewing/adding/editing/deleting, all allowed etc. These need to be set out clearly in the SOP of the facility.

ROS (Review of Systems): A series of questions related to the system(s) that the patient is having complaints about (i.e. respiratory for cold symptoms).

RxNorm: RxNorm is the name of a US-specific terminology in medicine that contains all medications available on US market; it provides normalized names for clinical drugs and links its names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software.

[S]

Secondary Care: Services provided by medical specialists who generally do not have first contact with patients (e.g., cardiologist, urologists, dermatologists). In the U.S., however, there has been a trend toward self-referral by patients for these services, rather than referral by primary care providers. This is quite different from the practice in England, for example, where all patients must first seek care from primary care providers and are then referred to secondary and/or tertiary providers, as needed.

Security Standards: The Security Standards require measures to protect the confidentiality, integrity and availability of e-PHI while it's being stored & exchanged. The security standard applies to all electronic PHI.

Security: This refers to the methods and techniques adopted to protect privacy and are a defense mechanism from any attack (Hong et al., 2004)

291

SNOMED: Systemized Nomenclature of Medicine Clinical Terms is the universal health care terminology. It is comprehensive and covers procedures, diseases, and clinical data. SNOMED CT helps to structure and computerize the medical record. It allows for a consistent way of indexing, storing, retrieving and aggregating clinical data across sites of care (i.e. hospitals, doctors offices) and specialties. By standardizing the terminology, the variability in the way data is captured, encoded and used for clinical care of patients and research is reduced. Allows for more accurate reporting of data. It is currently available in English, Spanish and German.

Social History: A description of a patient's social habits and history including marital status, alcohol and drug use and exercise habits.

Solo Practice, Solo Practitioner: A physician who practices alone or with others but does not pool income or expenses. This form of practice is becoming increasingly less common as physicians band together for contracting, overhead costs and risk sharing.

SOP: Standard operating procedures or protocols

SQL: Structured Query Language – is a computer language aimed to store, manipulate and retrieve data stored in relational databases.

SDO: Standards Development Organization – an organization responsible for development and maintenance of a standard or several, usually run on a not-for-profit basis.

Subjective: Section in a progress note where a patient's account of their current problem is documented. Consists of chief complaint, HPI and ROS.

Sx: Abbreviation for symptoms

[T]

T1, T3 line: A high-speed internet connection provided via telephone lines often used by businesses needing internet connection speeds greater than DSL/Cable.

Therapeutic Alternatives: Strong Drug products that provide the same pharmacological or chemical effect in equivalent doses. Also see Drug Formulary.

TPA: Third Party Administrator

Treatment Episode: The period of treatment between admission and discharge from a modality, e.g., inpatient, residential, partial hospitalization, and outpatient, or the period of time between the first procedure and last procedure on an outpatient basis for a given diagnosis. Many healthcare statistics and profiles use this unit as a base for comparisons.

Treatment: The provision of health care by one or more health care providers. Treatment includes any consultation, referral or other exchanges of information to manage a patient's care.

290

GLOSSARY

[V]

Vital Statistics: Statistics relating to births (natality), deaths (mortality), marriages, health, and disease (morbidity). Vital statistics for the United States are published by the National Center for Health Statistics. Vital statistics can be obtained from CDC, state health departments, county health departments and other agencies. An individual patient's vital statistics in a health care setting may also refer simply to blood pressure, temperature, height and weight, etc.

VPN: Virtual Private Network – A VPN "tunnel" is a secure connection, typically firewall to firewall that provides for remote access to your data server.

[W]

WHO: The World Health Organization is a specialized agency of the United Nations that is concerned with international public health.

[X]

XML (Extensible Markup Language): Used for defining data elements on a Web page and communication between two business systems. Example: Standard messaging system for and EMR to integrate with another software such as a practice management or drug formulary database.

289.

Contact Information

e-Governance Division
Department of Health & Family Welfare
Ministry of Health & Family Welfare
Government of India
mohfw.nic.in

Implementation specific queries may be referred to:
National Release Center (NRC)
VC&BA, Centre for Development of Advanced Computing (C-DAC)
Savitribai Phule Pune University Campus
Ganeshkhind Road
Pune – 411007
Email: nrc-help@cdac.in
http://www.snomedctnrc.in

288

Ministry of Health & Family Welfare
e-Governance Division

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Subject: Meeting of EHR review committee
Venue: 406-A Wing. Time: 11:00 AM. Date: 24th February, 2016.

S. No.	Name	Designation	Official Address	e-mail ids	Mobile Number	Sign
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8.	B. S. BEDI	Advisor, Health Informatics	C-48, Tarang Aptts. 19, IP Ext. Delhi-92	bsbedi11@gmail.com	9868243335	

Subject: **Meeting of EHR Review Committee on 24th February, 2016 at 11.00 AM in Nirman Bhawan, New Delhi.**

Date: 02/12/16 11:59 AM
From: "Amit Kumar" <amit.k89@gov.in>

To: "Prof. Supten Sarbadhikari" <supten@gmail.com>,
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Meeting Notice

Subject: Meeting of EHR Review Committee on 24th February, 2016 at 11.00 AM in Nirman Bhawan, New Delhi.

Ministry of Health and Family Welfare notified Electronic Health Record (EHR) Standards in September 2013 to encourage standardization, integration and electronic information exchange amongst the various healthcare providers.

2. EHR Review Committee has been constituted in MoHFW with the approval of Secretary (HFW) to review the aforementioned standards.

3. The third meeting of the EHR Review Committee under the Chairmanship of Shri Sunil Sharma, JS (eGov) has now been scheduled for 11**.00 AM on 24th February, 2016** in Room No 406-A wing, Nirman Bhawan, New Delhi.

4. All the addressees are requested to kindly make it convenient to attend the meeting as per the above schedule.

To:

1. Dr Supten Sarbadhikari, Project Director (NHP), NIHFW
2. Ms. Kavita Bhatia, Scientist 'E', DeitY
3. Shri Jitendra Arora, Director (eGov), MoHFW
4. Dr. S B Bhattacharya, Head Health Informatics, TCS
5. Dr B.S. Bedi, Advisor, CDAC, Delhi
6. Shri. Gaur Sunder, CDAC, Pune
7. Shri. Sunil Kumar Bhushan, NIC, Health

8. Dr. Karanvir Singh, CIO, Apollo Hospitals
9. Ms Shobha Mishra Ghosh, Senior Director, FICCI
10. Dr. Rajesh Narwal, Technical Director, Health System Regulations, WHO
11. Mr Amit Mishra, Senior Consultant, NHSRC
12. PL (ePMU team), MoHFW

Copy to:

1. PPS to AS (KBA), MoHFW
2. PPS to JS (eGov), MoHFW

No. Q-11011/3/2015-eGov

235

Government of India / भारत सरकार
D/o Health and Family Welfare/ स्वास्थ्य एवं परिवार कल्याण विभाग
e-Governance Section /(ई-गवर्नेंस अनुभाग)

*****

निर्माण भवन, नई दिल्ली
दिनांक: फरवरी, 2016

Meeting Notice / बैठक नोटिस

Subject: **Meeting of EHR Review Committee on 24th February, 2016 at 11.00 AM in Nirman Bhawan, New Delhi.**

Ministry of Health and Family Welfare notified Electronic Health Record (EHR) Standards in September 2013 to encourage standardization, integration and electronic information exchange amongst the various healthcare providers.

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(जितेंद्र अरोड़ा)
निदेशक (ई गवर्नेंस)
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
फोन : 23062317

To:

1. Dr Supten Sarbadhikari, Project Director (NHP), NIHFW
2. Ms. Kavita Bhatia, Scientist 'E', DeitY
3. Shri Jitendra Arora, Director (eGov), MoHFW
4. Dr. S B Bhattacharya, Head Health Informatics, TCS
5. Dr B.S. Bedi, Advisor, CDAC, Delhi
6. Shri. Gaur Sunder, CDAC, Pune
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Copy to:

1. PPS to AS (KBA), MoHFW
2. PPS to JS (eGov), MoHFW

284

R-21016/4/2014-eGov(TM)
Government of India / भारत सरकार
D/o Health and Family Welfare/ स्वास्थ्य एवं परिवार कल्याण विभाग
e-Governance Section /(ई गवर्नेंस अनुभाग)
*****

निर्माण भवन, नई दिल्ली
दिनांक: फरवरी, 2016

Notice / नोटिस

Subject: **Meeting of the Project Review and Steering Committee (PRSC) for iNRC for SNOMED-CT on 24.02.2016 regarding**

The Fourth meeting of the **Project Review and Steering Committee (PRSC) for iNRC for SNOMED-CT** under the chairmanship of Shri Sunil Sharma, JS, MoHFW has been scheduled on 24.02.2016 at 12.30 PM in Room No.406 A-wing, Nirman Bhawan, New Delhi to review the status/progress of iNRC and to decide the future course of action of CDAC as iNRC for SNOMED CT for India.

2. All the addressees are requested to kindly make it convenient to attend the meeting as per the above schedule.

(जितेंद्र अरोड़ा)
निदेशक (ई गवर्नेंस)
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
फोन : 23062317

To:

1. Dr. B.S Bedi, Advisor, Health Informatics, C-DAC
2. Mr. Gaur Sunder, Group Coordinator in charge, C-DAC
3. Mr. Arvind Sivaramakrishnan, CIO, Apollo Hospitals
4. Dr. Debashish Dutta, Scientist G, DeitY
5. Prof. T V Prabhakar, IIT, Kanpur
6. Prof, Rajeev Kumar, AIIMS, Delhi
7. Prof. Supten Nath Sarbadhikari, PD, CHI

Copy to: PPS to JS(SS)

Amit Kumar <amitkumariss34@gmail.com>

Fwd: DRAFT Policy for EHR Adoption

1 message

Jitendra Arora <dir.ehealth@gmail.com> Fri, Feb 5, 2016 at 1:34 PM
To: "Shrivastava, Chandrasen (IN - Delhi)" <chandrasens@deloitte.com>, Amit Kumar <amitkumariss34@gmail.com>, ANKIT TRIPATHI <ankit_tripathi11@hotmail.com>
Cc: Gurcharan Rajal <mr.rajal@gmail.com>

Kindly see and discuss
Regards

Jitendra Arora
Director(eHealth)
Ministry of Health and Family Welfare
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---------- Forwarded message ----------
From: **Gaur Sunder** <gaurs@cdac.in>
Date: Tue, Feb 2, 2016 at 5:28 PM
Subject: DRAFT Policy for EHR Adoption
To: Jitendra Arora <dir.ehealth@gmail.com>, jitendra.arora@gov.in
Cc: bsbedi11@gmail.com, Rajendra Joshi <rajendra@cdac.in>

Dear Sir,

Kindly recall that in a meeting held on 14-Dec-2015 with JS (eHealth) at MoH&FW, I was asked to propose a study for policy and strategy for accelerating the adoption of EHR in the country.

My team and I undertook studying national program of few countries to understand the best practices as well as extent of adoption and impediments thereof. We also brainstormed on methods and approaches that can used in our counties owning to its unique nature and challenges.

Based on our understanding of the current situation, approaches taken by other countries, and our own healthcare system and state, we have prepared a DRAFT National EHR Adoption Policy for your kind perusal. The document is attached.

I request you to please share the same with JS (eHealth) and others as suitable.

Regards
Gaur Sunder

[C-DAC is on Social-Media too. Kindly follow us at:
Facebook: https://www.facebook.com/CDACINDIA & Twitter: @cdacindia]

This e-mail is for the sole use of the intended recipient(s) and may

282

National EHR Adoption

January 15
2016

Draft of the policy of MoH&FW on to accelerate and promote nation-wide EHR Adoption. The Appropriate Authority / Committee can make necessary amendments as required before enforcement.

Policy

281

Contents

1 Executive Summary …… **2**

2 Introduction …… **3**

- 2.1 Current Scenario …… 3
- 2.2 Health Care Delivery in India …… 3
  - *2.2.1 Overview of EHR / EMR in India* …… *4*
- 2.3 International Experience and Best Practices …… 5

3 Strategies: …… **7**

- 3.1 Goal: …… 7
- 3.2 Technical …… 7
  - *3.2.1 Building an EHR Integration and Exchange Platform* …… *7*
  - *3.2.2 Technical Support Group* …… *8*
  - *3.2.3 Standards Compliance and Certification Framework* …… *8*
  - *3.2.4 Interoperability* …… *8*
- 3.3 Implementation …… 8
  - *3.3.1 Implementation Stages* …… *8*
  - *3.3.2 Motivation for Adoption* …… *10*
- 3.4 Governance …… 10

4 Policy Directions …… **10**

- 4.1 Awareness programmes for EHR Benefits and Standards Compliance …… 10
- 4.2 Motivations for Adoption …… 10
- 4.3 Mandate Use of Certified EHRs through Certification Framework …… 11
- 4.4 Provision of Technical Support Group …… 11
- 4.5 Strategies for Monitoring Phase wise Rollout of Implementation …… 11

5 References: …… **11**

6 Glossary / Definitions …… **12**

280

1 Executive Summary

India today is on the verge a major transition in the field of healthcare.The E-Health initiatives as part of the Digital India project aims to increase access to quality healthcare for all citizens by enabling information flow, facilitating collaboration through the use of ICTs and providing timely, economic health services. The adoption of Electronic Health Records (EHR) at a national level will act as a catalyst in this transition and change the face of the entire healthcare sector.

EHRs help providers deliver better health care by providing accurate, up-to-date, and complete information about patients at any point of care. It enables quick access to patient records for more managed, coordinated and efficient care.

EHRs create a greater and more seamless flow of information within a digital health care infrastructure, encompass and leverage digital progress thus transforming the way care is delivered and compensated. EHRs would ensure that information of a patient is available whenever and wherever it is needed.

The patients and health care providers can both reap the rich benefits of EHR if they are adopted in public as well as private sector across the country; facilitate good evidence-based medicine (EBM) systems and clinical data analytics. This will also impact the medical tourism profoundly.

This adoption needs to be strategically planned for a phase by phase roll out and not necessarily be a big bang event. Thus, there is need for National EHR Adoption policy which will act as a roadmap in achieving a single EHR for a patient.

Initially, MoH&FW, Government of India, and later the proposed National E-Health Authority (NeHA) will establish mechanisms and monitor the EHR Adoption policy to facilitate EHR adoption at a national level. [1]

Proposed goal objectives in implementing this policy comprise of technical, implementation and governance aspects.

Building a robust technical support structure, ensuring usage of standards compliant systems by way of certification, incentive based program to motivate uptake of EHR/EMR and a governance of this complex endeavor is essential.

This policy elaborates on the adoption to be rolled out over the next two decades considering the vast geographic expanse and the numerous healthcare providers providing services to over a billion Indians.

2 Introduction

Electronic Health Records (EHR), and Electronic Medical records (EMR), are mainly used to manage patient's health information. However, both are more or less the same with a difference in the scope of use and spread of time.EMR is mainly used by a single healthcare organization while EHR is collecting the patient information from different EMRs.EHR has the capability to store patient's information electronically, support decision making and health information exchange.

Worldwide, use of EHR in healthcare is increasing considerably in order to enhance the efficiency of healthcare.

To improve upon the rate of adoption in both the public and private sector, certain regulations and policies need to be in place. Thus, there is a dire need to have a national EHR adoption policy to strategize roll-out and maintain course of action.

The policy will take into consideration the current situation and factors affecting a widespread and quickened adoption of EHR and explore measures to motivate and support such activities.

2.1 Current Scenario

Although EMR has several tangible and intangible benefits, the adoption has been low. The present scenario is that only a handful of hospitals use EMR or HMIS/HIS with ability to record clinical information. The usage of EMR is limited to few hospitals in the handfulof cities of India.

Healthcare organizations have complex work practices including interdependency on roles, and a hierarchy of distributed responsibilities. This interdependency affects the change management while designing and implementing an EMR. The failure rate of EMR implementation is considered to behigh due to various factor including users and staff inconvenience caused bythe changes in their workflow.

A look at the current healthcare delivery structure in India, the factors affecting EMR adoption and a study of developed countries which have a good success rate in EHR / EMR adoption will be beneficial in charting out a road map for this endeavor in our country.

2.2 Health Care Delivery in India

The healthcare delivery structure is broadly divided into public and private sectors along with indigenous systems of medicines and national health programs.

The Public Health Sector mainly comprises of:

- Primary Health Care: It includes primary health centres and sub-centres.
- Hospitals / Health Centres: These include community health centres, rural hospitals, District Hospitals:Health centres, specialist hospitals and medicalcolleges.
- Health insurance Schemes like Employee State Insurance Scheme and Central Govt. Health Scheme
- Other important agencies like paramilitary, defense, and railways which have their own set of hospitals

The Private Health Sector includes Private Hospitals, clinics, polyclinics, nursing homes, dispensaries and individual practitioners (general and specialist).

Apart from the practice of Allopathy India also has its own indigenous system of medicine like Ayurveda, Siddha, and other systems that have found widespread use such as, Unani and Homeopathy.

Voluntary health agencies and National health programmes also play a major role in delivering healthcare services.

For a successful EHR / EMR adoption the above structure should be taken into consideration so that it is all inclusive. Although EHR / EMR are data collection, storage, retrieval and sharing systems and hence, can be used for any system of medicine, the standardization of data, terminologies, etc. are inclined towards Allopathy system. The set of EHR standards notified by MoH&FW, Government of India, with exception of reference logical model and terminologies, are mostly relevant in all systems of medicine. [2]

For purpose of widespread roll-out and continuous usage of EHR / EMR system, the usage scenario may also need to be in consonance with National Health Policy objectives.[3]

2.2.1 Overview of EHR / EMR in India

In the current scenario, very few comprehensive studies of the adoption of EMR by healthcare providers in India are available. Some State Govt. are proactive in taking up e-health initiatives and some major chain of hospitals are trying to utilize the advantages of an EMR. But in comparison to developed nations, the adoption of EMR in India is drastically low. The low adoption rate can be attributed to the following factors:

- The prevailing low awareness about the advantages of EHR / EMR among the small and medium scale healthcare service providers.
- Doctors and stakeholders operating within a hospital are reluctant toswitch to the EHR / EMR citing time involved, cost involved, etc.
- Lack of Standards compliance and basic ICT infrastructure. The large and medium organizations have proper ICT infrastructure but may or may not have standards compliant software. The small organizations and some government healthcare facilities still lack basic ICT infrastructure.
- Change management is often a daunting task in a healthcare organization and poses obstacles in adoption.
- Lack of training to users of EMRs which include the clinician community, nursing community and other users may or may not be available or sufficient.
- Owing to lack of Policy and regulatory gap the EMR adoption may or may not be taken seriously and depends on the healthcare organization.
- Perception of high cost of setup and operation as manyclinicalEMRsarepart of HIMS which are quite expensive to implement and maintain.
- Power and Communication medium failures or poor speed or general unreliability.
- Phase wise implementation process affects the ongoing clinical workflow in the hospital.
- The vendor community lacks domain knowledge of healthcare standards which results in development of incompatible products.
- Products especially with complicated EMR interfaces discourage clinicians in adoption as many find the user interfaces ascumbersome and inadequate.

277

A majority of healthcare providers in India still use paper-based documentation. Most providers do not maintain any outpatient clinical record. Some secondary and tertiary care organizations have adopted state-of-the-art healthcare information technology (IT) systems and may be aware of EHRs butprimary care organizations have very less or no information regarding EHRs.

2.3 International Experience and Best Practices

As India moves towards the national EHR adoption, it can take inspiration from several international good practices, some of them more than a decade old. In this section four countries of different size (geographical and population) who have adopted nationwide EHR adoption programs are given. There are several other countries, small and big, who have also similar program. The section is to highlight the approaches taken and reported successes.

Australia's NEHTA was established over a decade ago with the expressed aim of preparing the health system for large-scale adoption of eHealth. As such, its achievements are substantial: some parts have already been made operational (identifiers and standardized eHealth records) while the foundations are in place for several other aspects like clinical documents and supply chains. NEHTA has taken a decade to establish these foundations.

NEHTA's governance structure is interesting. It is implemented as a corporation, "co-owned" by States and Centre. It is an inspiration to know how NEHTA has achieved a greater involvement of the State governments, by making them partners in the reflection and implementation phases but also increasing their responsibility by making them co-owners.

Involvement of States is likely to be a big challenge in India, with its federal structure and "health being a State subject". [4]

Canada's Health Infoway (Infoway) helps to improve the health of Canadians by working with partners to accelerate the development, adoption and effective use of digital health across Canada. It helps deliver better quality and access to care and more efficient delivery of health services for patients and clinicians. Infoway is an independent, not-for-profit organization funded by the federal government. Canadian primary care EMR adoption and use continues to grow.

As of December 8, 2015 (Toronto) , more and more Canadian physicians are embracing digital health according to the recently released Commonwealth Fund's 2015 International Health Policy Survey of Primary Care Doctors. In fact, nearly three-quarters (73 per cent) of Canadian primary care physicians report using an electronic medical record (EMR), improving from 23 per cent in the 2006 survey results.Electronic Medical Records use has tripled in nine years.

More than 70 per cent of Canadian primary care physicians that use EMRs are using them to generate information that can support patient care; this includes information such as lists of all laboratory results and medication lists for patients, as well as pulling a practice-wide list of patients by diagnoses list.

Infowayco-invested with most of the provinces and territories in Canada to encourage EMR software use in community-based physicians' offices. These EMR systems are also connected to Electronic Health Record (EHR) systems outside the practice, which provides access to valuable clinical information, such as lab results, medication information, or hospital discharge reports. As of

276

September 30, 2015, over 19,000 community-based physicians and/or nurse practitioners are benefitting from Infoway EMR investments. [6]

ThusInfowayplays an important role as a "strategic investor" which helps in the global development of eHealth in the country.It also coordinates the development and maintenance of standards for EHR by way of directly helping in adoption of standards by keeping alignment to standards as a pre-condition for funding.

United States of America's EHR Incentive Program is based onThe American Recovery and Reinvestment Act of 2009 and Social Security Act for establishing incentive payments to eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs), and Medicare Advantage Organizations to promote the adoption and meaningful use of interoperable health information technology (HIT) and qualified electronic health records (EHRs). These incentive payments are part of a broader effort under the HITECH Act to accelerate the adoption of HIT and utilization of qualified EHRs. This effort is rolled out in two stages.

The Stage 1: Final rule set the foundation for the Medicare and Medicaid EHR Incentive Programs by establishing requirements for the electronic capture of clinical data, including providing patients with electronic copies of health information.

The Stage 2:Final rule expanded upon the Stage 1 criteria with a focus on ensuring that the meaningful use of EHRs supported the aims and priorities of the National Quality Strategy. Stage 2 criteria encouraged the use of health IT for continuous quality improvement at the point of care and the exchange of information in the most structured format possible.

The report from the Office of National Coordinator (ONC) Health Information Technology reports indicate that adoption of EHR systems by non-federal acute care hospitals has steadily increased since HITECH.In 2013, nearly 59% non-federal acute care hospitals had adopted at least a Basic EHR with clinician notes. This represents 34% increase from the previous year and a more than five-fold increase in EHR adoption since 2008.In addition, a vast majority of acute hospitals (93%) possessed EHR Technology certified as meeting federal requirements for Meaningful Use objectives.

In addition to growth in EHR adoption overall, hospital adoption of advanced functionality has increased significantly. Hospital adoption of comprehensive EHR systems has increased more than eight-fold in the last four years.

An incentive program suitable in Indian context can be designed to motivate hospitals and individual practitioners. [7]

Singapore's National Electronic Health Record (NEHR) is an integrated healthcare record system centred on an individual. It extracts and consolidates into one record clinically relevant information from the patient's encounters throughout the life across the public and private healthcare system. This information is stored and is accessible to the patient's authorized healthcare providers.

With the NEHR, the patient experience greater convenience while his authorized healthcare team are able to make more accurate clinical decisions to better support his care.

Benefits of NEHR:

- Timely and up-to-date clinical information at the point of care in support of key clinical decisions that can avoid delays in treatment.
- Reduce or avoid unnecessary treatments, tests and adverse events resulting in lower healthcare expenses for patients.
- Better prescribing practices, reduced waiting times and better management of the quality and cost of healthcare.

Singapore's healthcare regulatory framework consists mainly of 2 parties; the regulator (comprising Ministry of Health along with its statutory boards) and the regulated (comprising public and private providers).

E-Licensing for Healthcare (eLIS) website is an online system for the healthcare institutions to apply for the Private Hospitals & Medical Clinics (PHMC) licence. The website contains all information on the PHMC guidelines/ directives, and licensing terms and conditions, and important announcements that the Ministry disseminates to all healthcare institutions for compliance. [8]

3 Strategies:

3.1 Goal:

The EHR adoption strategies are to be established and implemented by all key stakeholders across India by the year 2020.

3.2 Technical

The technical aspects will play a crucial role in the success of the EHR adoption. Thus the technical strategies would include effectively building anationwide EHR integration and exchange platform by a longitudinal collection from all sources, provision of a technical support group, establishing standards compliance and certification network, and ensuring interoperability among disparate healthcare systems.

3.2.1 Building an EHR Integration and Exchange Platform

EHR is patient centric, cross institution/organization and longitudinal whereas an EMR is provider-centric, Institution/organization based and episodic.Initial step would be to motivate institutions and organizations in adoption of EMR.MoH&FW, Government of India has already notified the standards to be used for various aspects and vendors and healthcare institutions can implement them. Similarly, open source and free software can be explored for use of clinicians and small healthcare setup. BharatNet mission network can be used for connectivity or subsidized connectivity plans can be provided to all healthcare providers.

EHR can then be built for each patient with unique identifiers by pulling data from such EMRs. A robust technical infrastructure would be required to build a scalable system for over billion users. Under DeitY, Ministry of IT & Communication grants, Centre for Development of Advanced Computing has developed such a clinical records integration platform that is scalable and multiple standards compliant among other features. Such platform can form the basis of nationwide EHR aggregation.

274

3.2.2 Technical Support Group

Setting up a technical support group comprising of experts in healthcare standards, clinicians vendors and technical experts will facilitate to overcome the technical obstacles faced by the implementers and fill up existing gaps in the clinical workflow and the technology used. This may also require strategic partnerships between the ICT and healthcare sectors.

In this regard, currently functioning *interim National Release Center* currently functioning for SNOMED CT can be upgraded to *National Resource Center for Healthcare Standards* with adequate infrastructure, manpower and funds. The Resource Center can be single point of contact for all technical support in all notified standards as well as undertake workshops, training programs, interactions, promotional activities to disseminate information, and also support adoption.

3.2.3 Standards Compliance and Certification Framework

Adherence to the notified EHR standards for India should be taken into account. Though initially it is a recommended approach, it should be mandated at a later stage in near future as it will ensure standardization of clinical data which is a very important factor in interoperability of EMRs and EHRs consequently.

The standards compliance can be ensured by establishing a certification frameworkby certifying authorities like STQC Directorate. STQC Directorate is already engaged in development of certificate scheme for same.

3.2.4 Interoperability

Use appropriate standards for communication to achieve interoperability among healthcare providers and the centrally created EHR systems. This will ensure the seamless flow of patient data and making it available at any point of time. This will require setting up and maintaining Repositories, Exchanges and Networks.

The EHR Standards for India as notified by MoH&FW, Government of India is currently optional and must be moved to mandatory rules under Clinical Establishments Act.

3.3 Implementation

The implementation of the national EHR adoption will include the roadmap broken down in stages, the broad timelines and the motivations for the adoption.

3.3.1 Implementation Stages

Implementation stages may be spanned over the next 20 years, four stages of 5 years each to ensure that considerable amount of time is allocated for the healthcare providers in the public and private sector to complete the adoption.

The implementation stages should take into account the healthcare delivery structure so as to have a strealined approach.

The organizations may start implementing from stage 1even if it is not required according to the road map.i.e the implementation activities may be concurrent. The mandation would be on the completion of the requirements at the end of the time frame as given in the roadmap.This will give sufficient amount of time to incorporate the Basic EHR requirements by all the involved stakeholders and especially the hospitals in the Defense and the Railways.

The figure below represents a brief outline or roadmap of the implementation stages that can be rolled out.

Stage 1 (3 years): Pathbreaking Selected states • Establishing required Registries • State HQ • Govt. Initiatives / Programs • Govt. Medical College Hospitals • Selected Labs & Diagnostic Centres • Selected Private Hospitals	**Stage 2 (5 years): Scaling** All states and UT • Expand Registries to cover all • State HQ • Govt. Initiatives / Programs • Govt. Medical College Hospitals • Large and Medium Hospitals • Labs & Diagnostic Centres
Stage 3 (5 years): Coverage All Providers • Individual practices • Private Healthcare Providers • District hospitals • Community Health Centres • Defense and Railways • Insurance	**Stage 4 (3 years): Grassroot** All Stakeholder • Public health surveillance system • Remote Centres connected by telehealth • Pull data from ASHA workers • Primary care/ secondary care

Figure 1: Suggested Implementation Stages

Stage 1 requires involvement from selected states (such as Kerala, Tamilnadu, Gujarat, and Haryana) which are already proactive in e-Health initiatives. This should include healthcare providers from public as well as private sectors. Major laboratories and Diagnostic centres should also be a part of the process from stage 1 and complete by the end of stage 2.

Stage 2 requires involvement from the remaining states. Success of stage 1 shall serve as a role model for other states to take the implementation further. Union territories should ensure their completion of adoption and report accordingly to the Central Govt.

Stage 3 requires all providers to implement EHR based IT systems. States need to penetrate deeper at the district and taluk level are involved in the process. Defense and Railways can initiate implementing right from Stage 1 or 2 depending upon their readiness in terms of healthcare IT infrastructure and allocated funds for investing in EMRs,but they must ensure that the adoption is completed by end of Stage 3.

Stage 4 In the last stage health related data from other sources like public health surveillance systems, Remote Centres connected by telehealth and medical data available through ASHA workers. Primary care centres will need to be interconnected with national-level network.

An adoption of atleast Basic EHR functionalities should be achieved in the stipulated time duration i.e by the year 2020.

3.3.2 Motivation for Adoption

The EHR adoption is a complex process and the success depends on various factors. Providing different ways of motivation would play a crucial role in the entire scheme. Motivations based on financial outcomes would have a major impact on the implementers and affect the appropriate uptake of the technology.

3.4 Governance

The federal structure of the country comprising of 29 States and 07 Union territories would require a strong governance structure in place to facilitate and monitor the implementation at various levels. As technology percolates efficiently from the higher strata to the lower strata which is evident from the use of IT and mobile in the country in the recent past.

Hence, a Top-Down approach is suggested. The Ministry of Health and Family Welfare (MoH&FW) and the proposed National e-Health Authority (NeHA) have a crucial role to play in the governance structure.NeHA can be envisioned as agency that treats States and Private healthcare providers as stakeholders in the entire program. The State Governments should take the initiative in the adoption ensuring timely deliverables and monitoring the regulatory requirements of standards compliance and certification. They shall then report the outcomes to the Central Government for the estimated duration.

4 Policy Directions

4.1 Awareness programmesfor EHR Benefits and Standards Compliance

Awareness programmes for EHR benefits and standards compliance should be conducted to reach out all the stakeholders included in the EHR adoption process. State Governmentsshould take appropriate initiatives for their states and make sure that it is percolated till the primary health care centres and the masses as well. Since the EHRs are patient-centric, citizens should also be aware or this endeavour as they would play a very important role in creating a positive pressure on the healthcare providers in up taking of EHR/ EMR.

Platforms like MyGov and social networking sites can be effectively used for awareness, promotion and proliferation of EHR benefits and Standards compliance. Similarly, National Resource Center for Healthcare Standards (proposed in earlier section) will undertake such activities at national level along with providing technical support.

4.2 Motivations for Adoption

Motivations involving financial outcomes could be in one or many forms as mentioned below:

- Incentive Program: Incentives for hospitals and individual users for using EHR / EMR.
- Claim Expenditure: EHR users (healthcare providers) can claim the expenses incurred in procuring and maintaining the EMR annually in hospital or in individual practice as tax refund up to a reasonable limit as per their size of operation.
- Avail Tax Rebate: Allow EHR-enable and using providers some percentage of tax rebate in consultation with the Income Tax Department and taxation rules.
- CGHS Inclusion Criteria: Mandating EHR adoption to be included in the CGHS scheme and other such schemes at State level.

271

- Avail Funding: Funding can be availed for EMR procurement and annual maintenance (in agreement to certain terms and conditions related to patient data access whenever required)from banks (in same lines as small scale industries) on very low interest rate and longer payment periods.
- Benefit to Patients: Patients that choose to undergo treatment at EHR-enabled hospitals/clinic may be allowed to claim part of treatment as tax refund. Similarly, insurance premiums may be reduced or claim amount limit may be enhanced for seeking treatment at EHR-enabled hospitals/clinics. This will incentivize end-beneficiaries to select those healthcare provider who have invested in EHR systems thereby indirectly incentivize their usage.
- Link Central Funds to EHR adoption: All Central Government funds to States or other entities for healthcare programs be linked to adoption and usage of EHR / EMR systems.

4.3 Mandate Use of Certified EHRs through Certification Framework

Mandating use of certified EHRs / EMRs would ensure the quality of managed patient care. This should be clearly mentioned in relevant policy documents and conveyed to all stakeholders.

Certification framework need to be in place with certifying authorities like STQC before mandating the adoption process. The concerned authorities should be notified and their readiness for up taking such certification needs to be confirmed.

4.4 Provision of Technical Support Group

A technical support group comprising of domain experts, technical experts, vendors etc. should be formulated to guide, advice and support EHR / EMR adoption at various levels. People from both public and private sector should be involved. Tie-ups with IT and networking companies should be considered. Certified domain experts should be encouraged to join the group. In the absence of such group, the EHR / EMR adoption process might be hampered when obstacles, technical snags etc. are faced.National Resource Center for Healthcare Standards (proposed in earlier section) will undertake such activities at national level.

4.5 Strategies for Monitoring Phase wise Rollout of Implementation

Monitoring of planned activities is also crucial in executing programmes and yielding required results or outcome. The outputs should be tangible and should be corrected in time if deviated from the proposed roadmap. Delegation of responsibility appropriately to State Govt. would help in effectively monitoring the rollout. State Govt. can use the existing healthcare delivery hierarchy and collect reports from private hospitals as well.

5 References:

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270

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6 Glossary / Definitions

Electronic Health Records (EHR) is one or more repositories, physically or virtually integrated, of information in computer processable form, relevant to the wellness, health and healthcare of an individual, capable of being stored and communicated securely and of being accessible by multiple authorized users, represented according to a standardized or commonly agreed logical information model .Its primary purpose is the support of life-long, effective, high quality and safe integrated healthcare.(ISO 18308:2011)

Electronic Medical Record (EMR)is a special case of the EHR, restricted in scope to the medical domain or at least very much medically focused (ISO/TR 20514).It can be defined in a five-level hierarchy of the EMR; Departmental EMR: contains a patient's medical information entered by a single hospital department (e.g. pathology, radiology, pharmacy); Inter-departmental EMR: contains a patient's medical information from two or more hospital departments; Hospital EMR: contains a patient's clinical information from a particular hospital; Inter-hospital EMR: contains a patient's medical information from two or more hospitals. EHR: A longitudinal collection of health information from all sources. (Classification of EMR systems, JAHIS, V1.1, Mar 1996).

Subject: **M2M Communication" related work being carried out by Deity : Discussion held in EHR Review Committee**

Date: 02/02/16 09:02 AM
From: Jitendra Arora <dir.ehealth@gmail.com>

To: "Prof. Supten Sarbadhikari" <supten@gmail.com>,
"Dr. S. B. Bhattacharyya" <sbbhattacharyya@gmail.com>,
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"Prakash, Bhanu (IN - Delhi)" <bhanuprakash@deloitte.com>,
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Macine to Machine communication- notesheet for EHR... (938kB)

Dear Sir / Madam,

In the last EHR Standards Review committee held on 14th December 2015 , healthcare delivery by leveraging M2M communication was discussed and current status of M2M enablement & initiatives taken by DeitY in terms of IoT enabled communication such as standardization , data platform management , available infrastructure etc. was being sought.

A brief regarding "M2M Communication " related work carried out by DeitY is enclosed for your kind consideration.

Regards

Jitendra Arora
Director(eHealth)
Ministry of Health and Family Welfare
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New Delhi - 110108.
+91-11-23062317 (Telefax),
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As discussed in the EHR standards committee meeting held on 14th December 2015 , a brief regarding "M2M Communication" related work being carried out by DeitY is outlined as under:-

1. M2M in India in terms of health penetration is in nascent stage and has to be standardized and is being taken care of in an utmost important manner. Seven of the world's leading information and communications technology (ICT) Standards Development Organizations (SDOs) launched a new global organization to ensure the most efficient deployment of machine-to-machine (M2M) communication systems. The new organization, called oneM2M, is developing specifications to ensure the global functionality of M2M-allowing a range of industries to effectively take advantage of the benefits of this emerging technology. One M2M is the alliance of the various major ICT SDOs including Japan, USA, China, Korea and European Union.

2. M2M in Healthcare domain is principally focused on Tele- medicine, Smart Ambulance etc. medical Council of India is also looking into various aspects of these M2M requirements and is coordinating with Ministry of Health and family Welfare on aspects of electronic Health Record (EHR) system, automated health management systems etc.

Deityis also leading by example in order to promote and regulate M2M communication in Healthcare domain apart from other verticals. These can be broadly summarized as under:-

- A notification dated February 2012 outlining guidelines & policies for telecom productsprocurement has been issued and various M2Mdeviceslike GPS, AMI, RFID, M2M Gateways, commented personal health devices etc. has been included in PMA (Preferential Market Access).

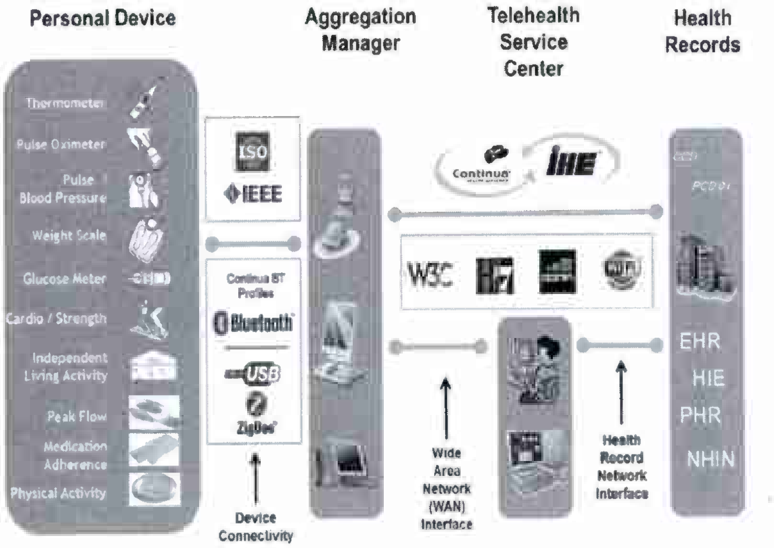
- DeitY proposes to create resource centers and test-beds &Demonstration Centersto help develop the IoT with 100% funding of 15 institutions to meet academic and research objectives, as well as one or two National Centers of Excellence to support "start-ups, [small- and medium-sized entities (SMEs)], students, and other innovators based on membership and support from design to prototype in productizing their ideas to encourage efficient manufacturing, apart from the product functional testingfor telecom equipment / sensors to ensure conformity to security and lawful interception standards& interoperability etc.

- Capacity building drive has been undertaken by TSSC (Telecom Sector Skill Council) in M2M domain

- DeitY in association with TIA (Telecommunication Industry Association)is also collaborating with the global stakeholders of IoT community for input and participation, and build upon existing standards activities from a variety of global standards organizations and industry-led standards coordination efforts already underway such as EHR standards ,oneM2M,BIS (Bureau of Indian Standards), ISO ,HIPPA, the Industrial Internet Consortium, IEEE 11073 Standards , Internet Engineering Task Force (IETF), and ISO/IEC JTC1, among others

- Creating & providing support to encourage & sustain IoT (Internet of Things) enabled communicationby leveraging IPv6 as standard for allocation of IP addresses to M2M devices

- Various M2M Service Delivery models for different industry verticals have been notified.The most suitable service delivery model for Health is Model 4 i.e. PAN operated Field Provider, Network Service Provider and M2M Service Provider.The typical deployment scenario for Tele health is illustrated in the Architecture Diagram as under:-



- M2M health working group has outlined following ISO & BIS standards governing the M2M architecture

ISO Standards for Health

ISO Standards	**Subject**
ISO En 13606	**Electronic health Communication (EHRCOM)**
ISO 13485:2003	**Medical Devices – quality management systems – Requirements for regulatory purposes**
ISO / TR 14969	**Medical devices – Quality management systems – Guidelines on the application of ISO 13485:2003**

Draft BIS Standards (Approved for circulation) for health

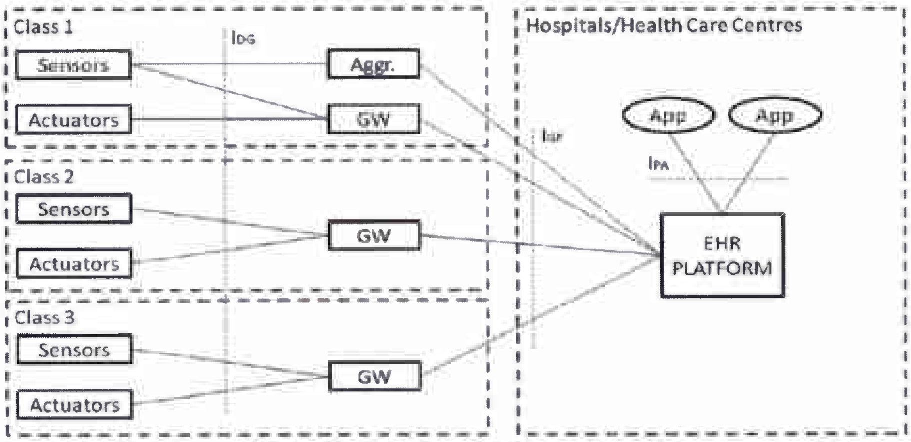
BIS Standards	Subject
DOC MHD 17 (0301)	Health informatics- good principles and practices for a clinical data warehouse ISO/TR 22221:2006

- Collaboration with oneM2M to finalize India specific policies with respect to existing standards such as Wireless - Spectrum and Radio Standards , Wire line Standards , Network Standards , Service and Information Standards , Application Standards is underway

- Working with **Personal Connected Health Alliance(PCHA),**collaboration between **Continua, m-Health Summit** and **HIMSS** focused on engaging consumers with an aim to facilitate the development and adoption of personal health solutions.DeitY would also create a **"national expert committee"** for developing and adopting IoT standards in India

- Medical devices categorization,Class 1/2/3,on the basis of factors like requiredcommunication infrastructure (USB, NFC, 6LowPAN, Wi-Fi, Zigbee,MPLS,PLC, 3G, 4G, etc.),data bandwidth, user interface& standard compliance etc.

- M2M network architecture for health vertical has been finalized and released by TEC wing of DeitY



Aggr – Aggregator
GW – Gateway
App – Application
EHR – Electronic Health Records

Class 1 – Mostly wellness/healthcare devices for temperature, BP, etc.
Class 2 – Glucometers, Robotic Injections, E.C.G patches, etc.
Class 3 – Implanted Devices like pacemakers and other critical devices.

The field side of the M2M network for health can be classified as Class 1, Class 2 and Class 3 depending upon the . Thedevices of these classes are connected to Aggregators or Gateways. The operator side of the M2Mnetwork for health connects the Gateways to the Medical platform.

- **TSDSI(Telecommunications Standards Development Society, India)**in coordination with **GCF (EU Global certification Forum)** is in charge of framing guidelines & policies for M2M products certification prior to commercial deployment.

- Finalization of M2M service provider(MSP) registration process .M2M service provider refers to healthcare company providing the Electronic health record system.

- Inter-ministerial consultation to boost M2M products and services

- Define procedures for energy rating of M2M devices & EMF radiation

- M2M Device / medical equipment's such as remote sensors , POS (point of Sale) manufacturing guidelines & medical device certification standards

- DeitY has proposed a common M2M Service Layer functional architecture, a standardized architecture with a common set of service layer capabilities with open interfaces and APIs encompassing all prominent verticals such as Health, Transport etc. to help M2M providers to reduce investments, time-to-market, development and on-boarding costs, and facilitate management of devices and applications.

- TEC (TelecomEngineeringCentre)Services and Development (S&D) Division in consultation with stake holders from the Government, Industry, standard bodies and sector users created a working group (WG) tofinalize M2Mgateway architecture & service delivery models derived on the basis of case scenarios in sectors & their technical analysis, key challenges in implementation etc.

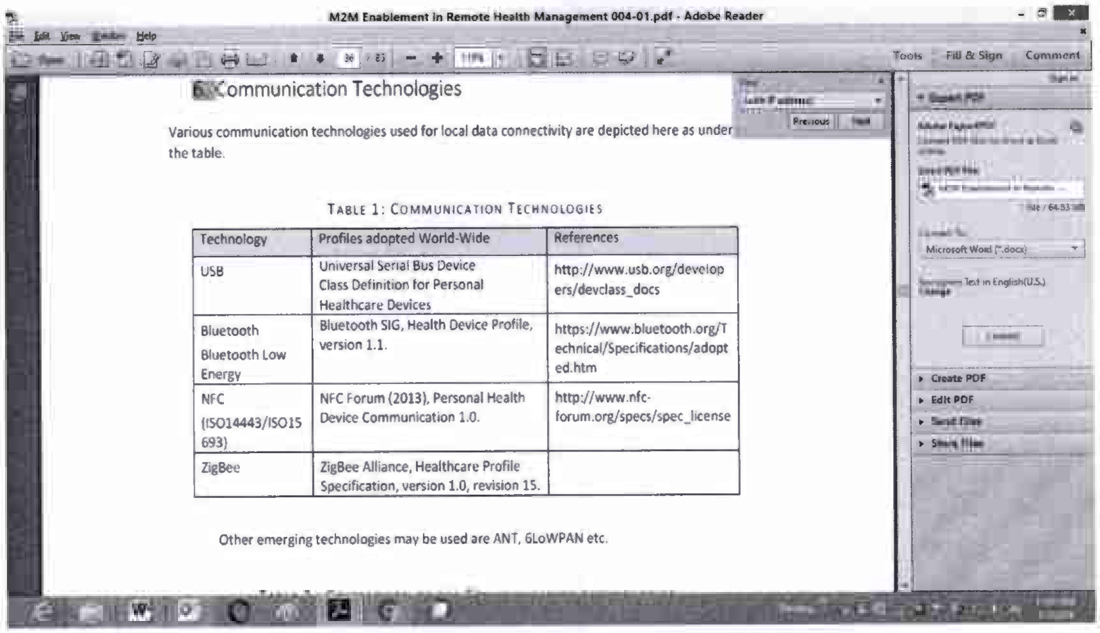
- DeitY is also in the process of finalizing the process of ascertaining the user identity through a gateway device - tablet or phone with SIM (with IP address). In this case, the tablet may have either a finger scanner for greater accuracy, or for cheap practical use, have a database of users, which the health personnel can select user identification from.Each personal health device may have a unique serial number managed by the manufacturer. The device installation or usage needs to be commissioned by way of registering the device for the user and linking it to the EHR system. The combination of the manufacturer and serial number shall provide unique ID to the device. For example, in USB communication systems, the device shall have a Vendor ID and a Product ID and a unique serial number. Aadhaar application may be used to identify the user of devices.

- DoT is also working on the part of data ownership & has notified that data relevant to M2M communication will lie with the user itself. However, since the rural user is not a technologically advanced user, the Ministry of Health, Government of India, will have to be involved in the processes and database management.

- Requirements Analysis for M2M Standards withrespect to existing Standards such as Wireless - Spectrum and Radio Standards , Wire line Standards , Network Standards , Service and Information Standards , Application Standards has been defined.

- Data compressing technologies (H.261,H.263,H.264/MPEG-4,H.265) coupled with encrypted data exchange by exchange of security keys between the communication channels using (AAA authentication)has been proposed.

3. Your consideration and valuable suggestions/ comments are required regarding interoperability and exchange of Electronic Health Records in terms of M2M communication. You are also requested to provide your inputs about any necessitated changes to be made in the concept of M2M in light of EHR standards.



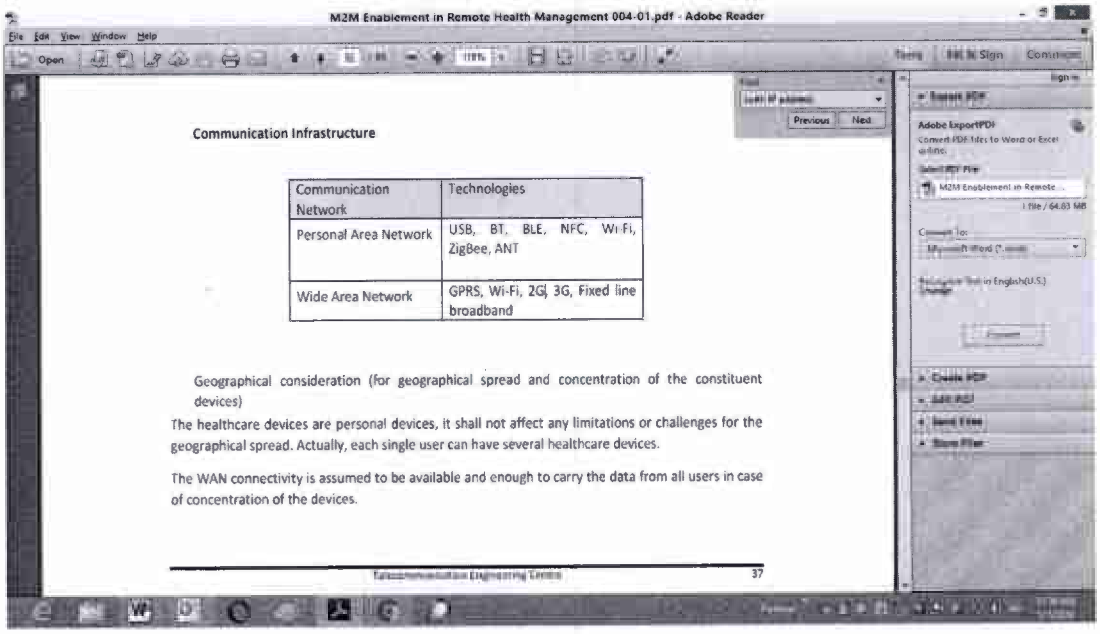
6. Communication Technologies

Various communication technologies used for local data connectivity are depicted here as under the table.

TABLE 1: COMMUNICATION TECHNOLOGIES

Technology	Profiles adopted World-Wide	References
USB	Universal Serial Bus Device Class Definition for Personal Healthcare Devices	http://www.usb.org/developers/devclass_docs
Bluetooth Bluetooth Low Energy	Bluetooth SIG, Health Device Profile, version 1.1.	https://www.bluetooth.org/Technical/Specifications/adopted.htm
NFC (ISO14443/ISO15693)	NFC Forum (2013), Personal Health Device Communication 1.0.	http://www.nfc-forum.org/specs/spec_license
ZigBee	ZigBee Alliance, Healthcare Profile Specification, version 1.0, revision 15.	

Other emerging technologies may be used are ANT, 6LoWPAN etc.


M2M Enablement in Remote Health Management 004-01.pdf - Adobe Reader
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Tools
Fill & Sign
Comment
Previous
Next
Adobe ExportPDF
Convert PDF files to Word or Excel online.
M2M Enablement in Remote ...
1 file / 64.83 MB
Create PDF

Communication Infrastructure

Communication Network	Technologies
Personal Area Network	USB, BT, BLE, NFC, Wi-Fi, ZigBee, ANT
Wide Area Network	GPRS, Wi-Fi, 2G, 3G, Fixed line broadband

Geographical consideration (for geographical spread and concentration of the constituent devices)

The healthcare devices are personal devices, it shall not affect any limitations or challenges for the geographical spread. Actually, each single user can have several healthcare devices.

The WAN connectivity is assumed to be available and enough to carry the data from all users in case of concentration of the devices.

Telecommunication Engineering Centre 37

Time Synchronization

The device may maintain its time locally. The device time can be synchronised with the server by the built-in function. This is a preferred requirement. The local storage of data will be time-stamped using the local time of the device. If the data is being updated on the server in real time, the EHR system will record the time as per the server time

Compliance to standard

- HIPAA (the defacto standard to comply with so that it becomes easier to pass the compliance test in other regions).

Suitable ISO and BIS standards - but these are not well defined for Medical Device based

Remote Patient Monitoring Scenarios in India. It is best to follow international standards to be future ready.

- Continua Health Alliance: International non-profit industry organization enabling end-toend, plug-and-play connectivity of personal health devices, systems and services in Personal Connected Health.
- IEEE 11073 Standards.

GVK EMRI has, through Tech Mahindra as its technological partner, been able to develop a comprehensive Emergency Management System. The organization in providing the below

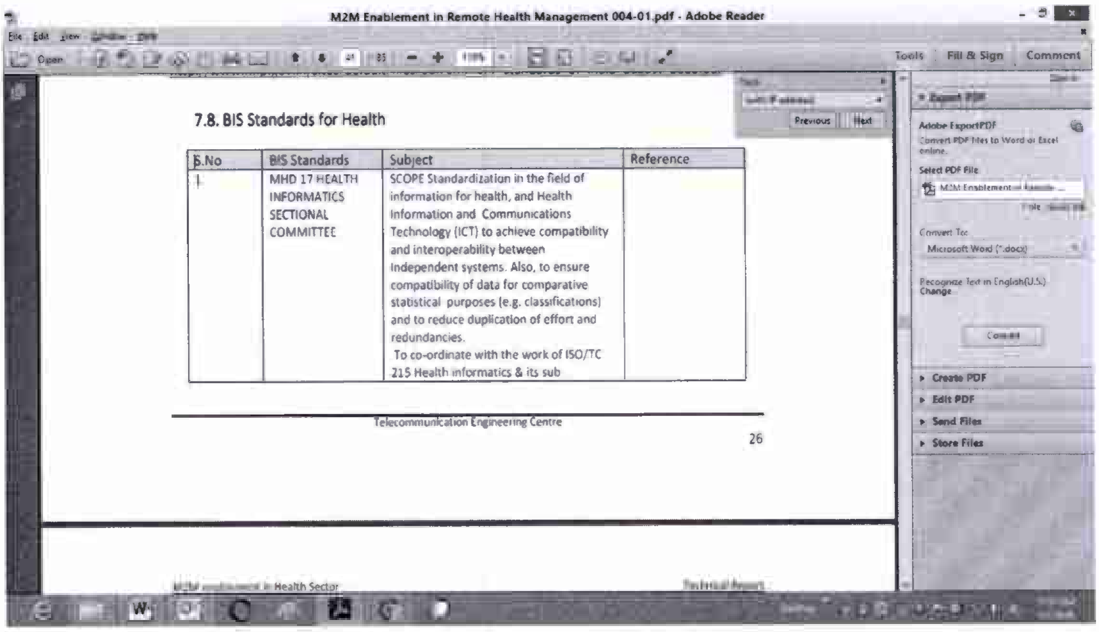
- Ensuring 24*7 availability of Network and Systems.
- Managing the Golden Hour efficiently.
- Ensuring a promptly assessed and hassle free helpline.
- Harnessing strong linkages/ partnerships/ alliances with hospitals, doctors, police, fire stations etc.
- Allows tracking of call based on location of caller.
- Enables Dispatch Officer to access the GIS Vector data (maps) provided by Government agencies and identify the incident location.
- Identifying the exact location of ambulance on real time basis.

Reference: http://www.emri.in/technology/

Automation of the processes involves the following major components of technology:

- Telecom Switch with automatic call distribution features & IVR facility
- Computer Telephony Integration
- Voice Loggers
- GIS/GPRS Software
- AVLT – Automatic Vehicle Location and Tracking
- Mobile Application

- 7.8. BIS Standards for Health



7.8. BIS Standards for Health

S.No	BIS Standards	Subject	Reference
1.	MHD 17 HEALTH INFORMATICS SECTIONAL COMMITTEE	SCOPE Standardization in the field of information for health, and Health Information and Communications Technology (ICT) to achieve compatibility and interoperability between independent systems. Also, to ensure compatibility of data for comparative statistical purposes (e.g. classifications) and to reduce duplication of effort and redundancies. To co-ordinate with the work of ISO/TC 215 Health informatics & its sub	

Telecommunication Engineering Centre

26

M2M enablement in Health Sector Technical Report

- **ITU-International Telecommunication Union**:- ITU has established a focus group on "M2M service layer" in 2012. FG M2M is mandated to identify a minimum set of common requirements of vertical markets, focusing initially on the health-care market, application programming interfaces (APIs) and protocols supporting e-health applications and services, and to draft technical reports in these areas.
- **Electronic Health Record Standards for India**:- Electronic Health Record Standards for India Government of India intends to introduce a uniform system for maintenance of Electronic Medical Records / Electronic Health Records (EMR / EHR) by the Hospitals and healthcare providers in the country

Subject: Re: Meeting of EHR Review Committee on 14th December, 2015 at 3.30 PM Nirman Bhawan, New Delhi

Date: 01/[illegible] PM

From: Jitendra Arora <dir.ehealth@gmail.com>

261

To: "Prof. Supten Sarbadhikari" <supten@gmail.com>,
"Dr. S. B. Bhattacharyya" <sbbhattacharyya@gmail.com>,
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"Dr. B.S. Bedi" <bedi11@yahoo.com>,
Sunil Kumar <sunil.bhushan@gov.in>,
drkaranvir_s@apollohospitals.com, sunil.sharma62@gov.in,
Shobha Mishra Ghosh <shobha.mishra@ficci.com>,
"NARWAL, Rajesh" <narwalr@who.int>

Cc: "Shrivastava, Chandrasen (IN - Delhi)" <chandrasens@deloitte.com:
"Prakash, Bhanu (IN - Delhi)" <bhanuprakash@deloitte.com>,
Agarwal K B AS <asfnd.kb@gmail.com>,
Amit Kumar <amit.k89@gov.in>

Dear Sir/Madam,

The 2nd meeting of the EHR Standards Review Committee was held on 14.12.2015 in Nirman Bhawan MoHFW under the chairmanship of JS(eGov.).

2. In the meeting draft suggestions for revision in the EHR Standards (2013) were presented by Shri B S Bedi, Shri Gaur Sunder and Shri Bhattacharyya and it was followed up with detailed deliberation.

3. hereafter as decided in the meeting, the draft suggested revisions in the EHR Standards was circulated to the Committee Members for their comments/suggestions. So far comments have been received from Apollo Hospitals, CHI (MoHFW), & WHO and are summarized below.

Dr Karanvir Singh Apollo Hospitals	Proposed revisions are fine.
Dr. S Sarbadhikari, PD, CHI	Proposed revisions are fine, except while **NeHA** is mentioned in the main body of Standards and Interoperability, it is missing from the Executive Summary and the Glossary.
Dr. Rajesh Narwal, WHO Also reviewed by Dr Mark Landry, Regional Advisor- WHO SEARO (on request of Dr Narwal)	Top-line comments/suggestions: 1. The overall suite of standards recommended are quite rational and complete. There is one new messaging standard that has just emerged which the MoHFW may consider-it's the health Aggregate Data Exchange (ADX) standard which effectively transacts both data and metadata for greater consistency. It is based on SDMX, which is robust. 2. The guide on revised HER standards could benefit from reference and linkages to an overall enterprise or health information exchange (HIE) architecture. We often use the Open HIE (www.ohie.org) architectural framework as a guide. For example, the application and use of the EHR standards can only enable full interoperability if the standards are organised into a terminology service layer (library) and all disparate systems and databases interact through an interoperability layer (enterprise service bus, for example). Without universal compliance with client, provider, facility registries--interoperability is not feasible. With a goal of having an overall shared health record, it is essential to place these EHR standards into the overall context of the (federated) EA.

3. As also mentioned during the meeting, the compliance and enforcement mechanisms for these standards will require further clarity. It is not necessarily cost effective or feasible for current system owners to re-engineer their solutions to comply with all the relevant standards to their system. The interoperability layer and use of such interim/intermediary solutions may also be needed. For example, compliance with the UIDAI aadhaar standard might take time, therefore it might be necessary to implement a national master patient index (MPI) to link all existing UIDs for individuals being used in such a way that a unique record for citizens can evolve from records already captured in localised EMRs or databases. OpenMPI is a good platform to help build this up and deal with de-duplication of records using probabilistic or deterministic matching.

4. The guide might also consider IHE profiles. These interoperability profiles in large part include the standards in this guide. However, they have already been tested, certified, implemented, and simply work. A number of specific use cases for EHR standards exist under many domains on the IHE website with complete implementation documentation. See http://wiki.ihe.net/index.php?title=Profiles and http://www.ihe.net/ for more details. Otherwise, the EHR guide is not clear just yet how the standards will exactly be used to address the many info exchanges required involving numerous standards for each transaction in many cases.

Additional remark : It would also be good to see any technical documentation on how SNOMED-CT would be implemented in India. If MoHFW has developed any use cases and interoperability profiles that include SNOMED CT, it might further be possible to advise on creating an overall national interoperability and standards framework along with use cases and profiles to justify and clarify how all the standards are necessary and will be used.

4. As decided in the last meeting (i.e. 2nd meeting) to meet next after one month and also internally discussed in e-Governance Division of MoHFW, it is desirable that 3rd meeting of the EHR Standards Review Committee be convened at the earliest to:

- discuss upon the comments received on the Draft Proposed Revisions & examine the same for appropriate incorporation in the revised draft
- chalk out future course of action with a time line

5. Accordingly the next meeting of the EHR Committee may be convened during 3rd week of **February 2016**. You are requested to kindly let us know your availability during these days.

I look forward to your confirmation so that date for the 3rd meeting could be finalized and arrangements be made accordingly.

Regards

Jitendra Arora
Director(eHealth)
Ministry of Health and Family Welfare
Nirman Bhawan (Room 307D)
New Delhi - 110108.

Subject: **RE: Meeting of EHR Review Committee on 14th December, 2015 at 3.30 PM in Nirman Bhawan, New Delhi.**

Date: 12/21/15 02:02 PM
From: "NARWAL, Rajesh" <narwalr@who.int>

[illegible]o: Jitendra Arora <dir.ehealth@gmail.com>,
"Prof. Supten Sarbadhikari" <supten@gmail.com>,
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Nikhil Malhotra <nimalhotra@deloitte.com>,
ANKIT TRIPATHI <ankit_tripathi11@hotmail.com>,
Amit Kumar <amit.k89@gov.in>

image002.jpg (3kB)

Dear Mr Arora,

Thank you for sharing the draft revised EHR standards. I had requested Dr Mark Landry, Regional Advisor- WHO SEARO (in CC) to review the EHR standards and he has been kind enough to oblige. Following are the top-line comments/suggestions for the consideration of the Expert Group;

The overall suite of standards recommended are quite rational and complete. There is one new messaging standard that has just emerged which the MoHFW may consider-it's the health Aggregate Data Exchange (ADX) standard which effectively transacts both data and metadata for greater consistency. It is based on SDMX, which is robust.

The guide on revised HER standards could benefit from reference and linkages to an overall enterprise or health information exchange (HIE) architecture. We often use the Open HIE (www.ohie.org) architectural framework as a guide. For example, the application and use of the EHR standards can only enable full interoperability if the standards are organised into a terminology service layer (library) and all disparate systems and databases interact through an interoperability layer (enterprise service bus, for example). Without universal compliance with client, provider, facility registries--interoperability is not feasible. With a goal of having an overall shared health record, it is essential to place these EHR standards into the overall context of the (federated) EA.

As also mentioned during the meeting, the compliance and enforcement mechanisms for these standards will require further clarity. It is not necessarily cost effective or feasible for current system owners to re-engineer their solutions to comply with all the relevant standards to their system. The interoperability layer and use of such interim/intermediary solutions may also be needed. For example, compliance with the UIDAI aadhaar standard might take time, therefore it might be necessary to implement a national master patient index (MPI) to link all existing UIDs for individuals being used in such a way that a unique record for citizens can evolve from records already captured in localised EMRs or databases. OpenMPI is a good platform to help build this up and deal with de-duplication of records using probabilistic or deterministic matching.

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It would also be good to see any technical documentation on how SNOMED-CT would be implemented in India. If MoHFW has developed any use cases and interoperability profiles that include SNOMED CT, it might further be possible to advise on creating an overall national interoperability and standards framework along with use cases and profiles to justify and clarify how all the standards are necessary and will be used.

I hope this feedback is useful, kindly let us know if you wish to discuss this further

Thanks and kind regards
Rajesh

Dr Rajesh Narwal, MD, MPH
Technical Officer- Health Systems Stewardship and Regulations
World Health Organization
Country Office- India
Phone: +91 11 66564800, GPN: 23232
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Web: http://www.searo.who.int/india/en/

*No 'Universal Health Coverage' without **effective Stewardship** (Policy Guidance/ Health System Design/ Collaboration & Partnerships/ Health intelligence & Oversight/ Regulation/ Accountability)*

From: Jitendra Arora [mailto:dir.ehealth@gmail.com]
Sent: 16 December 2015 15:26
To: Prof. Supten Sarbadhikari; Dr. S. B. Bhattacharyya; kbhatia@gov.in; Gaur Sunder; Dr. B.S. Bedi; Sunil Kumar; drkaranvir_s@apollohospitals.com; sunil.sharma62@gov.in; Shobha Mishra Ghosh; NARWAL, Rajesh
Cc: Shrivastava, Chandrasen (IN - Delhi); Prakash, Bhanu (IN - Delhi); Agarwal K B AS; Nikhil Malhotra; ANKIT TRIPATHI; Amit Kumar
Subject: Re: Meeting of EHR Review Committee on 14th December, 2015 at 3.30 PM in Nirman Bhawan, New Delhi.

[illegible]ct: **Re: Meeting of EHR Review Committee on 14th December, 2015 at 3.30 PM in Nirman Bhawan, New Delhi.**

Date: 12/16/15 03:24 PM
From: Jitendra Arora <dir.ehealth@gmail.com>

To: "Prof. Supten Sarbadhikari" <supten@gmail.com>,
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ANKIT TRIPATHI <ankit_tripathi11@hotmail.com>,
Amit Kumar <amit.k89@gov.in>

EHR Standards for India - 2015 - Final Draft - 4 N... (81kB)

Dear All,

The 2nd meeting of the EHR Review Committee was held at 330 PM on 14.12.2015 in Nirman Bhawan MoHFW under the chairmanship of JS(eGov.).

In the meeting draft suggestions for revision in the EHR Standards (2013) were presented by Shri B S Bedi, Shri Gaur Sunder and Shri Bhattacharyya followed with detailed deliberation.

A copy of the draft suggested revisions in the EHR Standards is enclosed for your kind review and comments/suggestions thereof in line with the discussion held in the subject meeting.

You are requested to kindly send your comments/ suggestions in the draft document enclosed by 28.12.2015

Regards

Jitendra Arora
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New Delhi - 110108.
+91-11-23062317 (Telefax),
+91-9868453680(Mobile)

On Tue, Dec 8, 2015 at 6:04 PM, Jitendra Arora <dir.ehealth@gmail.com> wrote:

Meeting Notice

Subject: Meeting of EHR Review Committee on 14th December, 2015 at 3.30 PM in Nirman Bhawan, New Delhi.

Ministry of Health and Family Welfare notified Electronic Health Record (EHR) Standards in September 2013 to encourage standardization, integration and electronic information exchange amongst the various healthcare providers.

2. EHR Review Committee has been constituted in MoHFW with the approval of

256

DRAFT

e-Governance Division
Department of Health & Family Welfare
Ministry of Health & Family Welfare
Government of India
mohfw.nic.in

ELECTRONIC HEALTH RECORD (EHR) STANDARDS FOR INDIA

OCTOBER 2015

Revised recommendations (over original August 2013 recommendations)

TABLE OF CONTENTS

TABLE OF CONTENTS

Contents

Executive Summary 1
Standards at a Glance 3
Standards and Interoperability 7
Health Record IT Standards 9
Guidelines 16
Data Ownership of Health Records 18
Data Privacy and Security 23
Glossary 28
Contact Information 44

253

EXECUTIVE SUMMARY

Executive Summary

INTRODUCTION

In September 2013 the Ministry of Health & Family Welfare (MoH&FW) notified the Electronic Health Record (EHR) Standards for India. The set of standards given therein were chosen from the best available and used standards applicable to Electronic Health Records from around the world keeping in view their suitability and applicability in India. The Committee constituted to recommend the standards drew from experts, practitioners, government officials, technologists, and industry. The notified standards were not only supported by professional bodies, regulatory bodies, stakeholders, but various technical and social commentators as well as being a step in the right direction. MoH&FW moved ahead with facilitating the adoption, as next steps, and in last two years the Ministry has made available standards like SNOMED CT free for use in country as well as appoint interim National Release Center (NRC) to handle this clinical terminology standard that is fast gaining widespread acceptance amongst the various healthcare IT stakeholder communities worldwide.

At the time of notifying the standards in September 2013, it was understood that the standards themselves will continue to evolve over time. Consequently, it was accepted that this notification will require revision from time to time. This becomes all the more necessary as understanding of those standards, their implementation and the expectations from the healthcare systems improve. Hence, MoH&FW constituted an expert group to review the earlier notified set of standards based on the experience and eyes firmly on the future. The set of standards provided herein represents the recommendations of the Expert Committee arrived at after deliberating on the various aspects of standardizations in healthcare record systems. The Committee also carefully examined the provisions of open standards and the guidelines as per the norms suggested by DeitY, MCIT, Government of India and recommended the standards given later in the document.

NEED FOR ELECTRONIC HEALTH RECORD

For a health record of an individual to be clinically meaningful it needs to be from conception or birth, at the very least. As one progresses through one's life, every record of every clinical encounter represents a health-related event in one's life. Each of these records may be insignificant or significant depending on the current problems that the person is suffering from. Thus, it becomes imperative that these records be available, arranged, and be clinically relevant to provide a summary of the various clinical events in the life of a person.

An Electronic Health Record (EHR) is a collection of various medical records that get generated during any clinical encounter or events. With rise of self-care and homecare devices and systems, meaningful healthcare data get generated 24x7 and also have long-term clinical relevance. The purpose of collecting medical records, as much as possible, are manifold – better and evidence based care, increasingly accurate and faster diagnosis that translates into better treatment at lower costs of care, avoid repeating unnecessary investigations, robust analytics including predictive analytics to support personalized care, improved health policy decisions based on better understanding of the underlying issues, etc., all translating into improved personal and public health.

EXECUTIVE SUMMARY

Without standards, a lifelong medical record is simply not possible, as different records from different sources spread across ~80+ years potentially needs to be brought meaningfully together. To achieve this, a set of pre-defined standards for information capture, storage, retrieval, exchange, and analytics that includes images, clinical codes and data is imperative.

STRATEGIC HIGHLIGHTS

This document provides a structured overview of the key EHR standards with respect to Indian healthcare system. For every aspect of data/information that is part of any healthcare record system has been addressed with a short guideline regarding implementation included. Various non-related recommendations from previous edition have been removed to better streamline the set of standards selected and achieve harmony among them. A detailed recommendation on the interoperability and standards, clinical informatics standards, data ownership, privacy and security aspects, and the various coding systems are given. The set of standards given in earlier edition has been updated with their latest versions as we move towards a better implementation.

LOOKING AHEAD

This document is a continuation of its earlier version, but in many ways reflects our growing confidence in path correctly chosen earlier – set of international and proven standards focused towards syntactic and semantic interoperability. The idea that any person in India can go to any health service provider/practitioner, any diagnostic center or any pharmacy and yet be able to access and have fully integrated and always available health records in an electronic format is not only empowering but also vision for efficient 21st century healthcare delivery.

In conclusion, it must be reiterated that these standards cannot be considered either in isolation or as "etched in stone for all eternity". These will need to undergo periodic review and update as necessary. Hence, this document must be a "living document".

STANDARDS AT A GLANCE

Standards at a Glance

This section is provided for quick reference. Details are provided in the subsequent sections. N.B., this is a tentative list only.

S. No.	Type	Standard Name	Intended Purpose
1	Identification & Demographics	ISO/TS 22220:2011 Health Informatics – Identification of Subjects of Health Care	Basic identity details of patient
2		MDDS – Demographic (Person Identification and Land Region Codification) version 1.1	Complete demographic for interoperability with E-Governance systems
3	Patient Identifiers	UIDAI Aadhaar	Preferable identifier where available
4		Local Identifier	Identifier given within institution / clinic / lab
5		Government Issued Photo Identity Card Number	Identifier in conjunction with local in absence of Aadhaar
6	Architecture Requirements	ISO 18308:2011 Health Informatics – Requirements for an Electronic Health Record Architecture	System architectural requirements
7	Functional Requirements	ISO/HL7 10781:2015 Health Informatics - HL7 Electronic Health Records-System Functional Model Release 2 (EHR FM)	System functional requirements
8	Reference Model and Composition	ISO 13940 Health informatics - System of Concepts to Support Continuity of Care	Concepts for care, actors, activities, processes, etc.
9		ISO 13606 Health informatics - Electronic Health Record Communication (Part 1 through 3)	Information model architecture and communication
10		openEHR Foundation Models Release 1.0.2	Structural definition and composition
11	Terminology	SNOMED Clinical Terms (SNOMED CT)	Primary terminology
12	Coding System	Logical Observation Identifiers Names and Codes (LOINC)	Test, measurement, observations
13		WHO Family of International Classifications (WHO-FIC) including ICD, ICF, ICHI, ICD-O	Classification and reporting

STANDARDS AT A GLANCE

S. No.	Type	Standard Name	Intended Purpose
14	Imaging	Digital Imaging and Communications in Medicine (DICOM) PS3.0-2015	Image, waveform, audio/video
15	Scanned or Captured Records	JPEG lossy (or lossless) with size and resolution not less than 1024px x 768px at 300dpi	Image capture format
16		ISO/IEC 14496 - Coding of Audio-Visual Objects	Audio/Video capture format
17		ISO 19005-1 Document Management - Electronic Document File Format for Long-Term Preservation - Part 1: Use of PDF 1.4 (PDF/A-1)	Scanned documents format
18	Data Exchange	ANSI/HL7 V2.8.2-2015 HL7 Standard Version 2.8.2 - An Application Protocol for Electronic Data Exchange in Healthcare Environments	Event/Message exchange
19		ASTM/HL7 CCD Release 1 (basis standard ISO/HL7 27932:2009)	Summary Records exchange
20		ISO 13606-5:2010 Health informatics - Electronic Health Record Communication - Part 5: Interface Specification	EHR archetypes exchange [Also, refer to openEHR Service Model specification]
21		DICOM PS3.0-2015 (using DIMSE services & Part-10 media/files)	Imaging/Waveform Exchange
22	Other Relevant Standards	Bureau of Indian Standards and its MHD-17 Committee	Standards Development Organizations (SDOs)
23		ISO TC 215 set of standards	
24		IEEE/NEMA/CE standards for physical systems and interfaces	
25	Discharge/ Treatment Summary	Medical Council of India (MCI) under regulation 3.1 of Ethics	Composition as prescribed
26	E-Prescription	Pharmacy Practice Regulations, 2015 Notification No. 14-148/ 2012- PCI as specified by Pharmacy Council of India	Composition as prescribed
27	Personal Healthcare and medical Device Interface	IEEE 11073 health informatics standards and related ISO standards for medical devices	Device interfacing
28	Data Privacy and Security	ISO/TS 14441:2013 Health Informatics – Security & Privacy Requirements of EHR Systems for Use in Conformity Assessment	Basis security and privacy requirements

STANDARDS AT A GLANCE

S. No.	Type	Standard Name	Intended Purpose
29	Information Security Management	ISO/DIS 27799 Health informatics - Information Security Management in Health using ISO/IEC 27002	Overall information security management
30	Privilege Management and Access Control	ISO 22600:2014 Health informatics - Privilege Management and Access Control (Part 1 through 3)	Access control
31	Audit Trail and Logs	ISO 27789:2013 Health informatics - Audit trails for Electronic Health Records	Audit trail
32	Data Integrity	Secure Hash Algorithm (SHA) used must be SHA-256 or higher	Data Hashing
33	Data Encryption	Minimum 256-bits key length	Encryption key
34		HTTPS, SSL v3.0, and TLS v1.2	Encrypted connection
35	Digital Certificate	ISO 17090 Health informatics - Public Key Infrastructure (Part 1 through 5)	Digital certificates use and management

***Note**: Where year of publication or version of standard (or its parts) is not provided explicitly, the latest published version of standard (or its parts) available from standard body as on the date of notification / circulation of this recommendation is to be used.*

248

List of Supporting / Complimenting Standards

The following list is indicative and representative and not comprehensive or definitive. These standards are advised to be used where applicable and as required.

S. No.	Standard	Description
1	ISO 12967:2009	Health Informatics - Service Architecture (Parts 1 - 3)
2	ISO 13972:2015	Health Informatics - Detailed Clinical Models, Characteristics and Processes
3	ISO 20301:2014	Health Informatics - Health Cards - General Characteristics
4	ISO 21090:2011	Health Informatics - Harmonized Data Types for Information Interchange
5	ISO 8601:2004	Data elements and Interchange Formats - Information Interchange - Representation of Dates and Times
6	ISO 13119:2012	Health Informatics - Clinical Knowledge Resources - Metadata
7	ISO 22857:2013	Health Informatics – Guidelines on Data Protection to Facilitate Trans-Border Flows of Personal Health Data
8	ISO 21549-1:2013	Health Informatics — Patient Healthcard Data — Part 1: General Structure
9	ISO TS 14265:2011	Classification of Purposes for Processing Personal Health Information
10	ISO TS 27527:2010	Health Informatics – Provider Identification

STANDARDS AND INTEROPERABILITY

Standards and Interoperability

INTEROPERABILITY STANDARDS

The primary aim of interoperability standards is to ensure syntactic (structural) and semantic (inherent meaning) interoperability of data amongst systems at all times. The need for that cannot be overstated, more so within healthcare information systems whose primary aim is to deliver life-long clinical care at all times so that the person being cared for is able to maintain his/her health.

The set of standards outlined in this document represents an incremental approach to adopting standards, implementation specifications; criteria to enhance the interoperability, functionality, utility, and security of health information technology; and to support its widespread adoption. It is to be kept in mind that these standards need to be flexible and modifiable to adapt to the demographic and resource variance observed in a country like India with its large population with diverse culture that is spread across a large region of varied geographical landscapes – hilly regions, river basins, desert, coast, etc. – many of which are remote and accessible with difficulty.

It is important to recognize that interoperability and standardization can occur at many different levels. To achieve interoperability, information models would need to be harmonized into a consistent representation.

In other cases, organizations may use the same information model, but use different vocabularies or code sets (for example, SNOMED CT or ICD10) within those information models. To achieve interoperability at this level, standardizing vocabularies, or mapping between different vocabularies may be necessary. For some levels, (such as the network transport protocol), an industry standard that is widely used (e.g. TCP/IP – Transmission Control Protocol and Internet Protocol) will likely be the most appropriate. Ultimately, to achieve true interoperability, it is anticipated that multiple layers – network transportation protocols, data and services descriptions, information models, and vocabularies and code sets – will need to be standardized and/or harmonized to produce an inclusive, consistent representation of the interoperability requirements.

It is further anticipated that using a harmonization process will integrate different representations of health care information into a consistent representation and maintain and update that consistent representation over time. For an information model, this process could include merging related concepts, adding new concepts, and mapping concepts from one representation of health care information to another. The need to support standardization of data and services descriptions and vocabularies and codes sets is appropriately addressed.

It is also recognized that a sustainable and incremental approach to the adoption of standards will require processes for harmonizing both current and future standards. This will allow the incremental updating of the initial set of standards, implementation specifications, and certification criteria and provide a framework to maintain them. The decision to adopt such updates will be informed and guided by recommendations from an appropriate authority such as the proposed National eHealth Authority (NeHA), Ministry of Health & Family Welfare or expert groups.

246

STANDARDS AND INTEROPERABILITY

GOALS

The goals of standards in electronic health record systems are:

- Promote interoperability and where necessary be specific about certain content exchange and vocabulary standards to establish a path forward toward semantic interoperability
- Support the evolution and timely maintenance of adopted standards
- Promote technical innovation using adopted standards
- Encourage participation and adoption by all vendors and stakeholders
- Keep implementation costs as low as reasonably possible
- Consider best practices, experiences, policies and frameworks
- To the extent possible, adopt standards that are modular and not interdependent.

245

Health Record IT Standards

IDENTIFICATION AND DEMOGRAPHIC INFORMATION OF PATIENT

Demographic information including a unique identifier is necessary in a health record system in order to capture identifying information as well as identifiers for linking other medical artifacts logically as well as physically. All health record systems must therefore adhere to the following standards for capturing information related to patient demography and identifiers:

1. ISO/TS 22220:2011 Health Informatics – Identification of Subjects of Health Care
2. MDDS – Demographic (Person Identification and Land Region Codification) version 1.1 from E-Governance Standards, Government of India

Implementation Guideline: Implementers must insure that health record application is able to capture all data fields as provided in the above two standards for completeness. It should also ensure that the system is able to interoperate (receive/import/send/export) all demographics information as provided in above two standards as per demand, i.e. when requested for demographics data in MDDS compliant format it should generate artefacts (file, message, etc.) as per that standard. Where codes related to location, authority, type of organization etc. are required, they should be taken from the MDDS-Demographic Standard.

A health record system must have provision to include patient identifiers of following types:

1. UIDAI Aadhaar Number (preferred where available)
2. Both of following in case Aadhaar is not available:
    2.1 Local Identifier (as per scheme used by HSP)
    2.2 Any Central or State Government issued Photo Identity Card Number

Implementation Guidelines:

1. Implementers must ensure that the Aadhaar number, where that is available, be used as the preferred identifier to serve as the unique health identifier. In case the Aadhaar number is not available, the system should allow a user to insert more than one (minimum two) identifiers for each patient along with its scope and provider (as given in above mentioned patient demography standards) in the system. In emergency situations where identity of patient cannot be confirmed or ascertained, temporary identifiers may be used (as per scheme used by HSP) and later confirmed identifiers may be inserted (while making earlier ones as inactive).
2. *Identification of Patient across EHR systems*: Due to lack of mandate for use of Aadhaar or any such alternative(s) national unique identifier, it is difficult to match patient records when exchanging them between two EHR systems. This may lead to situations where different combinations of local identifier and photo identity card numbers of the same person are used at different locations and/or in solutions.

244

Thus, a single person may get to have different identities under which his/her records are captured. A conflict resolution process may be required to help resolve such cases. At this time, there is no direct solution available other than to use smart (possibly heuristic) algorithms to attempt to match records without or with intervention/confirmation of a human supervisor. Such an algorithm may use name (phonetic or spelling), address (full or parts), date of birth / age, gender, or other such matching details to mark incoming or searched records as possible or exact match before amalgamation or subsequent use. ISV may additionally need to provide the ability to merge/demerge patients to support this process within their solutions.

ARCHITECTURE REQUIREMENTS AND FUNCTIONAL SPECIFICATIONS

A health record system must meet architectural requirements and functional specifications to remain faithful to the needs of service delivery, be clinically valid and reliable, meet legal and ethical requirements, and support good medical practices. Therefore, a health record system must conform to the following standards:

1. ISO 18308:2011 Health Informatics – Requirements for an Electronic Health Record Architecture
2. ISO/HL7 10781:2015 Health Informatics - HL7 Electronic Health Records-System Functional Model Release 2 (EHR FM)

Implementation Guideline: Above two standards, despite being extensive, are not full set of specifications and requirements to be met by a health record system or its many variants (PHR, etc.) or all possible use cases. The above mentioned standards are to be used as minimum set to be used within the scope of implementation as per relevance to the system being developed / deployed.

LOGICAL INFORMATION REFERENCE MODEL AND STRUCTURAL COMPOSITION

A health record system must accumulate observable data and information for all clinically relevant events and encounters. For this purpose, it is important to have common semantic and syntactic logical information model and structural composition for captured artefacts. Unless the data being captured is standardized, its communication and understanding may not be same across systems. Therefore, a health record system must conform to the following standards:

1. ISO 13940 Health Informatics - System of Concepts to Support Continuity of Care
2. ISO 13606 Health Informatics - Electronic Health Record Communication (Part 1 though3)
3. openEHR Foundation Models Release 1.0.2
    3.1 Required Model Specifications: Base Model, Reference Model, Archetype Model
    3.2 Optional Model Specifications: Service Model, Querying, Clinical Decision Support

Implementation Guideline: The ISO 13940 (also known as CEN ContSys) is to be generally used for purpose of modelling and describing concept system and organize information objects. While ISO 13606 set of

243

standards are basic reference model and related specifications, openEHR provides ISO 18308 conformant platform-independent implementation harmonized with ISO 13606 standard. Implementers are free to design internal structures, databases, and user interfaces as per the requirements and technology platforms but structural composition for clinical data/information artefact must be logically similar to Reference Model given in above standards. A health record system implementation must make its openEHR compliant Operational Templates (OPT) freely available and accessible in required format.

MEDICAL TERMINOLOGY AND CODING STANDARDS

In order to have semantic interoperability between different health record systems, it is necessary to follow a common terminology and coding system standards to express unambiguous meaning of data captured, stored, transmitted, and analyzed. It is also important to have these terminologies and codes in computer process-able format to aid automation and ensure that data is in an analyzable state at all times. Therefore, a health record system must conform to the following standards:

1. Primary Terminology: IHTSDO - SNOMED Clinical Terms (SNOMED CT)

Implementation Guideline: A health record system must use SNOMED CT as the primary internal encoding system for all clinically relevant, including dental, nursing, substance/drugs, information. IHTSDO SNOMED CT code shall also be used while communicating clinical information to other health record systems. SNOMED CT concept codes (as pre-coordinated or as post-coordinated expressions) are to be used for all hierarchies covered under the standard unless otherwise provided in this document. It shall also be the coding system that must be used internally in other information storage and communication standards such as openEHR archetypes, HL7, DICOM, etc. IHTSDO releases SNOMED CT twice annually.

2. Test, Measurement and Observation Codes: Regenstrief Institute - Logical Observation Identifiers Names and Codes (LOINC)

Implementation Guideline: LOINC coding is to be used for processing results and reports with Laboratory and Imaging Information Systems. N.B.: SNOMED CT to LOINC coding interchange map is available from IHTSDO and Regenstrief Institute.

3. Classification Codes: WHO Family of International Classifications (WHO-FIC)

   3.1 WHO ICD-10: International Classification of Diseases (ICD) and its derivative classifications

   3.2 WHO ICF: International Classification of Functioning, Disability and Health (ICF)

   3.3 International Classification of Health Interventions (ICHI)

   3.4 International Classification of Diseases for Oncology (ICD-O)

Implementation Guideline: WHO FIC codes are primarily used for aggregated information and statistical/epidemiological analysis for public health purposes derived from health records that contain patient care related information as well as information that is crucial for management, health financing and

242

general health system administration. While SNOMED CT is to be used by health record systems for terminology, generated classification-based reports may require the use of WHO FIC codes. Classification based reporting, for statistical or regulatory purposes, may continue to use WHO FIC codes as mandated by the health regulatory, intelligence, and various research bodies. N.B.: SNOMED CT to ICD-10 coding interchange map is available from IHTSDO and WHO.

DATA STANDARDS FOR IMAGE, MULTIMEDIA, WAVEFORM, DOCUMENT

A health record system stores data records and files of various types in support of clinical functions. These data elements serve the purpose of documentary records of various diagnostic and prescriptive data or information generated. Therefore, a health record system must conform to the following standards for such data:

1. NEMA Digital Imaging and Communications in Medicine (DICOM) PS3.0-2015

Implementation Guideline: NEMA DICOM PS3.0-2015 is a comprehensive standard for handling and managing image (series or single), waveforms (such as those in ECG/EEG), audio (such as those in digital-stethoscope) and video (such as those in endoscope, ultrasound) data in medicine. A health record implementation is required to implement relevant DICOM Information Object Definitions (IODs) for supported data types in Part-10 compliant files. Where required and relevant, other features of standard such as services, display, print, and workflow may be implemented.

2. Scanned or Captured Records:

   2.1 Image: JPEG lossy (or lossless) with size and resolution not less than 1024px x 768px at 300dpi

   2.2 Audio/Video: ISO/IEC 14496 - Coding of Audio-Visual Objects

   2.3 Scanned Documents: ISO 19005-1 Document Management - Electronic Document File Format for Long-Term Preservation - Part 1: Use of PDF 1.4 (PDF/A-1)

Implementation Guideline: The above mentioned standards are to be used for documentary data (scan for prescription, summaries, etc.) and data captured through traditionally non-DICOM compliant sources like picto-micrographs, pathological photographs, photographs of intramural and extramural lesions, etc. All data formats that can be converted into relevant DICOM format should be, as relevant, converted and communicated as secondary captured DICOM format. It may be noted that while no maximum image resolution has been prescribed, a sufficiently acceptable limit may be used to avoid unnecessarily large file that do not aid in correspondingly better diagnosis or analysis.

DATA EXCHANGE STANDARDS

A health record system has to operate in a larger ecosystem of other components with which it must share or communicate data in order to capture and provide as comprehensible medical information as is practical. A health record system must therefore conform to the following standards:

HEALTH RECORD IT STANDARDS

1. Event/Message Exchange: ANSI/HL7 V2.8.2-2015 HL7 Standard Version 2.8.2 - An Application Protocol for Electronic Data Exchange in Healthcare Environments
2. Summary Records Exchange: ASTM/HL7 CCD Release 1 (basis standard ISO/HL7 27932:2009)
3. EHR Archetypes: ISO 13606-5:2010 Health informatics - Electronic Health Record Communication - Part 5: Interface Specification [Also, refer to openEHR Service Model specification]
4. Imaging/Waveform Exchange: NEMA DICOM PS3.0-2015 (using DIMSE services& Part-10 media/files)

Implementation Guideline: Implementation of exchange standards is expected to be at least for the scope of data captured or retained by the health record system. To explain further, full implementation of ANSI/HL7 V2.8.2 for each event and message is not required in health record systems but minimum implementation supporting the types of events and messages relevant to the system is required. Similarly, implementation/support of DICOM DIMSE C-Store and/or C-FIND/C-GET service is expected for IODs supported by health record system whereas implementation of WADO could be optional.

OTHER STANDARDS RELEVANT TO HEALTHCARE SYSTEMS

Healthcare record systems need to co-exist within a larger ecosystem with various other systems. It is important for all systems within a healthcare setup to adhere to relevant standards. While standards related to such systems are not within the scope of this document, as a general rule, standards created or ratified by following Standard Development Organizations (SDOs) should be used:

1. Bureau of Indian Standards and its MHD-17 Committee
2. ISO TC 215 set of standards
3. IEEE/NEMA/CE standards for physical systems and interfaces

Implementation Guideline: To help the implementers, an indicative list of such standards is provided in the "Standards at a Glance" section above. BIS approved standards shall be preferred for implementation.

DISCHARGE/TREATMENT SUMMARY FORMAT

Implementers must ensure that the logical information model includes data elements to satisfy requirements of the format for Medical Records as specified by Medical Council of India (MCI) under regulation 3.1 of ethics. The printed reports will need to be in the MCI prescribed format whenever any discharge or treatment summary is prepared.

E-PRESCRIPTION

Pharmacy Council of India (PCI) has, in its recent regulation (Pharmacy Practice Regulations, 2015 Notification No. 14-148/ 2012- PCI), provided the definition of the term under Section 2(j) that the term

240

'Prescription' includes the term 'electronic direction'. Implementers must therefore ensure that the logical information model includes data elements to satisfy requirements of the format for Medical Prescription as specified by the Pharmacy Council of India. The printed prescription will need to be in the PCI prescribed format whenever any medical prescription meant for drug dispensing is prepared. For the purpose of e-Prescription, implementers must ensure that the electronic version is digitally signed by a registered medical practitioner, and its non-repudiation is ensured at all times. The pharmacists shall be able to print a copy of e-Prescription in the required format along with other relevant digital authentication details.

PERSONAL HEALTHCARE AND MEDICAL DEVICES INTERFACING

Where not covered under relevant data exchange standards, it is recommended that IEEE 11073 health informatics standards and related ISO standards for medical devices be followed as appropriate whenever any personal healthcare/medical device is interfaced with the EMR system for the purpose of clinical data exchange, retrieval, storage, etc.

PRINCIPLES OF DATA CHANGE

The data once entered into a health record system must become immutable. The healthcare provider may have the option to re-insert/append any record in relation to the medical care of the patient as necessary with a complete audit trail of such change maintained by system. Alteration of the previously saved data should not be permitted. No *update* or *update like* command shall be accessible to user or administrator to store a medical record or part thereof. Any record requiring revision should create a new medical record containing the changed/appended/modified data of earlier record. This record shall then be stored and marked as ACTIVE while rendering the previous version(s) of the same record marked INACTIVE. The data will thus be immutable. A strict audit trail shall be maintained of all activities at all times that may be suitably reviewed by an appropriate authority like auditor, legal representatives of the patient, the patient, healthcare provider, privacy officer, court appointed/authorized person, etc.

As-Is Principal:

The data captured through the devices is usually in a certain format whereas the data given by the doctor as file may be in some different format. These data provided / included in the system is to be treated as sacrosanct. The As-Is Principal requires that the data captured in the first instance should be retrievable at any given point of time later in the same format, clarity, size and detail as it was provided in the beginning.

It effectively means that the system is not allowed to make any changes either to the data or its format or its nature at any point other than the creation time for any reason. However, if it is required that the data needs to be altered either to carry some additional information at some later point, like annotation on images, or correction of errors of omission or commission, etc., it must be done on a copy of the original data, keeping the original data intact, and marking the updated version as active while marking the previous version inactive. The modified data will become part of the EHR/EMR.

Informed Format Change:

Whenever, the data, its format or its nature needs to be changed within the system, it must be done with the explicit consent of the doctor / technician / person that is entering or managing the data. This explicit consent can also be taken from a set of preferences already set by the user or the administrator / root of the system. In such preference based consent, there is no need to prompt the user for permission at each insertion point.

Also, in case the system is set to change format or nature of data automatically by setting of preferences, it must be made sure that the rule of conversion is declared in the Standard Operating Procedure (SOP) of site/application.

Guidelines

HARDWARE

- The IT hardware used should meet (and preferably be better than) the optimal requirements specified by the software (to be) used.
- The medical and IT hardware used must meet the relevant applicable specifications from BIS, NEMA, IEEE, ISO, CE, RoHS, EnergyStar, apart from Medical and IT standards for the equipment.
- A backup or data preservation mechanism should be considered. Data capacity should be planned to meet the storage requirement as per the mandated rule/law.
- System redundancy at various levels (disk, power, network, etc.) should be planned to meet the organizational system availability requirement.
- Network and data security should be planned, implemented, and periodically audited. Please see section on Security and Privacy for the various requirements and functions that need to be supported and implemented.
- Hardware should be checked periodically for correctness and completeness of operation expected from them. An appropriate maintenance cycle should be planned and rigorously followed.
- Planned and expected Capacity and Quality requirement of the organization should be met by the hardware used. Periodic updates and upgrades should be carried out to meet the requirements.

NETWORKING AND CONNECTIVITY

- Should be able to harness any telecommunications-related connectivity like the Internet, LAN, WAN, WAP, CDMA, GSM or even Cloud Computing that will permit the various EMRs of an individual to be integrated into a single lifelong electronic health record
- As far as is practical and affordable, the connectivity medium chosen should be reliable and fast enough to sustain a secure data exchange for the period expected for transaction of records and data. The speed of the connectivity medium should be chosen from among available options so as to provide an acceptable user experience and not cause software/system fault due to delays/noise/failure.
- Should be able to ensure that data exchange is performed in a secure manner to ensure data validity and non-repudiability
- The data exchange must further ensure that data integrity is maintained at all times

SOFTWARE STANDARDS

The software for capturing, storing, retrieving, viewing, and analyzing healthcare records should:

- Conform to the specified standards
- Satisfy specified requirements
- Be Interoperable, especially in terms of syntax and semantics of the information being exchanged

GUIDELINES

- Should be able to ensure user authentication and authorization
- Should be able to support privacy, secrecy and audit trail
- Possess advanced search, merge, and demerge functionality to ensure that duplicates are robustly resolved
- Should be able to support conception-to-current/most recent medical records of a person (as relevant to scope of application)
- Should be able to support digital archiving and retrieval of medical records after the death of a person for the total duration as specified by Government of India from time to time
- Should be able to construct a medical/clinical summary based on available records from the very first visit to current/most recent
- Preferably be able to support rapid data capture-storage-retrieval-display of data

HEALTH RECORD IN MOBILE DEVICES

As people become more mobile and travel becomes more accessible, patients will increasingly expect the healthcare record system to provide essential health information over mobile devices, which will give their treating clinician basic information like, medical condition, drug/allergy information etc. Demographics, insurance info, medications, allergy and alerts, and vital signs are some of the records that are recommended to be provided in at least read-only manner and to the extent relevant for emergency care and quick reference. It is also possible that certain clinical (BP, temperature, glucose count) and lifestyle (steps walked, distance run, sleep duration and quality) related information will additionally be provided by the patient thereby providing vital clues and information on the overall wellbeing of patient.

In the specific regard of design and usability of such applications, m-governance guidelines of DeitY, Ministry of Communication & Information Technology, Government of India shall be applicable. (http://www.deity.gov.in/content/framework-mobile-governance).

Data Ownership of Health Records

THE ETHICAL, LEGAL, SOCIAL ISSUES (ELSI) GUIDELINES

For the purposes of these recommendations, the term "privacy" shall mean that only those person or person(s) including organizations duly authorized by the patient may view the recorded data or part thereof. The term "security" shall mean that all recorded personally identifiable data will at all times be protected from any unauthorized access, particularly during transport (e.g. from healthcare provider to provider, healthcare provider to patient, etc.). The term "trust" shall mean that person, persons or organizations (doctors, hospitals, and patients) are those who they claim they are.

The following approaches are to be adopted wherever applicable to address the aspects that the terms mentioned above refer to:

- Privacy would refer to authorization by the owner of the data (the patient)
- Security would have as components both public and private key encryption; the encryption techniques used in transit and at rest need to be through different methodologies.
- Trust would be accepted whenever a trusted third party confirms identity

PROTECTED HEALTH INFORMATION

Protected Health Information (PHI) would refer to any individually identifiable information whether oral or recorded in any form or medium that (1) is created, or received by a stakeholder; and (2) relates to past, present, or future physical or mental health conditions of an individual; the provision of health care to the individual; or past, present, or future payment for health care to an individual.

Electronic Protected Health Information (ePHI) would refer to any protected health information (PHI) that is created, stored, transmitted, or received electronically. Electronic protected health information includes any medium used to store, transmit, or receive PHI electronically.

As per the Information Technology Act 2000, Data Privacy Rules, refer to 'sensitive personal data or information' (Sensitive Data) as the subject of protection, but also refer, with respect to certain obligations, to 'personal information'. Sensitive Data is defined as a subset of 'personal information'. Sensitive Data is defined as personal information that relates to:

1. Passwords
2. Financial information such as bank account or credit card or debit card or other payment instrument details
3. Physical, psychological and mental health condition
4. Sexual orientation
5. Medical records and history
6. Biometric information
7. Any detail relating to (1) – (6) above received by the body corporate for provision of services

235

8. Any information relating to (1) – (7) that is received, stored or processed by the body corporate under a lawful contract or otherwise

DATA OWNERSHIP

- The physical or electronic records, which are generated by the healthcare provider, are held in trust by them on behalf of the patient
- The contained data which are the sensitive personal data of the patient is owned by the patient herself.
- The medium of storage or transmission of such electronic medical record will be owned by the healthcare provider.
- The "sensitive personal information (SPI) and personal information (PI)" of the patient is owned by the patient themselves. Refer to IT Act 2000 for the definition of SPI and PI.

DATA ACCESS AND CONFIDENTIALITY

- Regulations are to be enforced to ensure confidentiality of the recorded patient/medical data and the patient should have a control over this.
- Patients will have the sufficient privileges to inspect and view their medical records without any time limit. Patient's privileges to amend data shall be limited to correction of errors in the recorded patient/medical details. This shall need to be performed through a recorded request made to the healthcare provider within a period of 30 days from the date of discharge in all inpatient care settings or 30 days from the date of clinical encounter in outpatient care settings. An audit of all such changes shall be strictly maintained. Both the request and audit trail records shall be maintained within the system.
- Patients will have the privileges to restrict access to and disclosure of individually identifiable health information and need to provide explicit consent, which will be audited, to allow access and/or disclosures.
- All recorded data will be available to care providers on an 'as required on demand' basis

DISCLOSURE OF PROTECTED / SENSITIVE INFORMATION

- For use in treatment, payments and other healthcare operations: In all such cases, a general consent must be taken from the patient or next of kin, etc. as defined by applicable laws by MCI.
- Fair use for non-routine and most non-health care purposes: a specific consent must be taken from the patient; format as defined by MCI.
- For certain specified national priority activities, including notifiable/communicable diseases, the health information may be disclosed to appropriate authority as mandated by law without the patient's prior authorization
- Instances where use and disclosure without individual authorization will be possible are as follows:
    - Complete record with all identifiers in an "as-is" state, on production of court order

234

  - Totally anonymized data, where the anonymization process involves the complete removal of all information that allows the identification of the patient. (List of such personally identifiable information is provided below)

RESPONSIBILITIES OF A HEALTHCARE PROVIDER

- Protect and secure the stored health information, as per the guidelines specified in this document
- While providing patient information, remove patient identifying information (as provided in the list below), if it is not necessary to be provided
- Will ensure that there are appropriate means of informing the patient of policies relating to her/his rights to health record privacy
- Document all its privacy policies and ensure that they are implemented and followed. This will include:
  - Develop internal privacy policies
  - Designate a privacy officer (preferably external, may be internal) who will be responsible for implementing privacy policies, audit and quality assurance
  - Provide privacy training to all its staff

PRIVILEGES OF PATIENT OR PERSONAL REPRESENTATIVE

Patient will have the privilege to appoint a personal representative to carry out the activities detailed below.

- Patients will have the privilege to ask for a copy of its medical records held by a healthcare organization.
- Patients will have the privilege to request a healthcare organization that stores/maintains his/her medical records, to withhold specific information that he/she does not want disclosed to other organizations or individuals.
- Patient can demand information from a healthcare provider on the details of disclosures performed on the patient's medical records for any reason whatsoever

DENIAL OF INFORMATION

Healthcare provider will be able to deny information to a patient or representative or third party, in contravention of normal regulations, if in the opinion of a licensed healthcare professional the release of information would endanger the life or safety of the patients and others. This will include but not be limited to as follows:

- Information obtained from an anonymous source under a promise of confidentiality.
- Psychotherapy notes.
- Information compiled for civil, criminal or administrative action.

233

DATA OWNERSHIP OF HEALTH RECORDS

ELECTRONIC MEDICAL RECORDS PRESERVATION

Preservation of medical records assume significant importance in view of the fact that an electronic health record of a person is an aggregation of all electronic medical records of the person from the very first entry till date. Hence, all records must compulsorily be preserved and not destroyed during the life-time of the person, ever.

Upon the demise of the patient where there are no court cases pending, the records can be removed from active status and turned to inactive status. ISVs are free to decide when to make a record inactive, however, it is preferable to follow the "three (3) year rule" where all records of a deceased are made inactive three (3) years after death.

It is however preferred and ISVs are strongly encouraged to ensure that the records are never be destroyed or removed permanently. The health of the blood relatives and natural descendants of the person can be strongly influenced by the health of the person and on-demand access to these may prove to be hugely useful in the maintenance of the health of the relations.

Furthermore, analysis of health data of all persons is expected to greatly benefit in the understanding of health, disease processes and the amelioration thereof.

With rapid decline in costs of data archiving coupled with the ability to store increasing amounts of data that may be readily accessible, continued maintenance of such data is not expected to lead to any major impact on the overall system maintenance and use.

PATIENT IDENTIFYING INFORMATION

Data are "individually identifiable" if they include any of the under mentioned identifiers for an individual or for the individual's employer or family member, or if the provider or researcher is aware that the information could be used, either alone or in combination with other information, to identify an individual. These identifiers are as follows:

- Name
- Address (all geographic subdivisions smaller than street address, and PIN code)
- All elements (except years) of dates related to an individual (including date of birth, date of death, etc.)
- Telephone, cell (mobile) phone and/or Fax numbers
- Email address
- Bank Account and/or Credit Card Number
- Medical record number
- Health plan beneficiary number
- Certificate/license number
- Any vehicle or other any other device identifier or serial numbers
- PAN number
- Passport number

232

- AADHAAR card
- Voter ID card
- Fingerprints/Biometrics
- Voice recordings that are non-clinical in nature
- Photographic images and that possibly can individually identify the person
- Any other unique identifying number, characteristic, or code

APPLICABLE LEGISLATION

The existing Indian laws including IT Act 2000 and their amendments from time to time would prevail (http://deity.gov.in/content/information-technology-act-2000).

DATA PRIVACY AND SECURITY

Data Privacy and Security

SECURITY OF ELECTRONIC HEALTH INFORMATION:

The Privacy Standards and the Security Standards are necessarily linked. Any health record system requires safeguards to ensure that the data is available when needed and that information is not used, disclosed, accessed, altered, or deleted inappropriately while being stored or retrieved or transmitted. The Security Standards work together with the Privacy Standards to establish appropriate controls and protections. Health sector entities that are required to comply with the Privacy Standards also must comply with the Security Standards.

Organizations must consider several factors when adopting security measures. How a healthcare provider satisfies the security requirements and which technology it decides to use are business decisions left to the individual organizations. In deciding what security measures to adopt, an organization must consider its size, complexity, and capabilities; it's technical infrastructure, hardware, and software security capabilities; the cost of particular security measures; and the probability and degree of the potential risks to the ePHI it stores, retrieves and transmits.

PURPOSE OF THE SECURITY STANDARDS

The security standards require healthcare providers to implement reasonable and appropriate *administrative*, *physical*, and *technical* safeguards to:

- ensure the confidentiality, integrity, and availability of all the e-PHI they create, transmit, receive, or maintain
- protect against reasonably anticipated threats or hazards to the security or integrity of their e-PHI
- protect against uses or disclosures of the e-PHI that are not required or permitted under the Privacy Standards
- ensure their workforce will comply with their security policies and procedures

TECHNICAL STANDARDS

To protect the ePHI handles by a healthcare provider, the provider must implement technical safeguards as part of its security plan. Technical safeguards refer to using technology to protect ePHI by controlling access to it. Therefore, they must address the following standards focusing on the following functionalities. It is worth noting that they will need to use an EHR/EMR solution that is able to successfully and robustly demonstrate the possession and working of these functionalities.

The basic requirements for security and privacy are provided in following standard:

1. ISO/TS 14441:2013 Health Informatics – Security & Privacy Requirements of EHR Systems for Use in Conformity Assessment

230

Authentication:

- Locally within the system the fact that a person or entity seeking access to electronic health information is indeed the one as claimed and is also authorized to access such information must be verifiable.
- Across the network, however extensive it might be, the fact that a person or entity seeking access to electronic health information across a network is the one claimed and is authorized to access such information in accordance with the standard specified in this document must be verifiable.

Automatic log-off: An electronic session after a predetermined time of inactivity must be forcibly terminated. To log in back, the user will have to initiate a new log in session. However, for the sake of ergonomics, it is recommended that the unsaved state of the system at the time of automatic log-off be saved and presented back to the user for further action. This should be a user-specific feature.

The advisory standard for overall information security management in health is:

2. ISO 27799 Health informatics - Information Security Management in Health using ISO/IEC 27002

Implementation Guideline: The ISO 27799 is provided as a basic advisory standard for security management. Other security management and standard / practices / guidelines given by Law (such as IT Act 2000 and amendments) or regulatory / statutory / certification bodies (such as National Accreditation Board for Hospitals & Health care Providers (NABH)) should be taken in consideration when designing and/or implementing health record system.

Access control: The solution must assign a unique name and/or number for identifying and tracking user identity and establish controls that permit only authorized users to access electronic health information. In cases of emergency where access controls need to be suspended in order to save a live, authorized users (who are authorized for emergency situations) will be permitted to have unfettered access electronic health information for the duration of the emergency with the access remaining in force during the validity of the emergency situation.

Access Privileges: Ideally only clinical care providers should have access rights to a person's clinical records. However, different institutional care providers have widely varying access privileges specified that are institution-specific. No country-wide standards can be specified for this at least at this point in time.

For privilege management and access control, following standards may be used:

3. ISO 22600:2014 Health informatics - Privilege Management and Access Control (Part 1 through 3)

Implementation Guideline: The ISO 22600 set of standards is provided as an advisory standard for policy based access control. For the purpose of privilege management, rule / policy based access is expected to give better control and flexibility in defining and enforcing access control. Access control mechanisms such

229

as Role Based, Policy Based, or singular user (applicable in case of mobile based PHR) are acceptable as long as conformant to applicable data security law(s) and rules as well as policy of the organization where implemented.

Audit log:

- All actions related to electronic health information in accordance with the standard specified in this document including viewing should be recorded.
- Based on user-defined events must be provided.
- All or a specified set of recorded information upon request or at a set period of time must be electronically displayed and printed.

The advisory standard for audit trail / log in health record system is:

4. ISO 27789:2013 Health informatics - Audit Trails for Electronic Health Records

Integrity:

- During data transit the fact that the electronic health information has not been altered in transit in accordance with the standard specified in this document must be verifiable.
- Detection of events – all alterations and deletions of electronic health information and audit logs, in accordance with the standard specified in this document must be detected.
- Appropriate verification that electronic health information has not been altered in transit shall be possible at any point in time. A secure hashing algorithm must be used to verify that electronic health information has not been altered in transit and it is recommended that the Secure Hash Algorithm (SHA) used must be SHA-256 or higher.

Encryption:

- Generally, all electronic health information must be encrypted and decrypted as necessary according to organization defined preferences in accordance with the best available encryption key strength (minimum 256-bits key).
- During data exchange all electronic health information must be suitably encrypted and decrypted when exchanged in accordance with an encrypted and integrity protected link.
- All actions related to electronic health information must be recorded with the date, time, patient identification, and user identification whenever any electronic health information is created, modified (non-clinical data only), deleted (stale and non-clinical data only), or printed; and an indication of which action(s) took place must also be recorded.

228

- A cross-enterprise secure transaction that contains sufficient identity information such that the receiver can make access control decisions and produce detailed and accurate security audit trails must be used within the system.
- Secure Transmission standards and mechanisms must be used to allow access to health information as well as transmit data from one application / site to another. For this purpose HTTPS, SSL v3.0, and TLS v1.2 standards should be used. Please refer to relevant IETF, IEEE, ISO, and FIPS standards for same.

Digital Certificates:

Use of Digital Certificates for identification and digital signing is recommended in health record system. Health record system must use following standard where digital certificates are used:

5. ISO 17090 Health informatics - Public Key Infrastructure (Part 1 through 5)

ADMINISTRATIVE SAFEGUARDS STANDARDS

The Administrative Safeguards require healthcare providers to develop and implement a security management process that includes policies and procedures that address the full range of their security vulnerabilities. Being administrative in nature, these need to be internally designed and developed as standard operating procedure (SOP) that must be published for all users to see and adhere to. Conformance to adherence may be delegated to the Privacy Officer detailed in the Data Ownership chapter above. To comply with the Administrative Safeguards, a healthcare provider must implement the following standards.

- The security management process standard, to prevent security violations;
- Assigned security responsibility, to identify a security officer;
- Workforce security, to determine e-PHI user access privileges;
- Information access management, to authorize access to e-PHI;
- Security awareness training, to train staff members in security awareness;
- Security incident procedures, to handle security incidents;
- Contingency plan, to protect e-PHI during an unexpected event; and
- Evaluation, to evaluate an organization's security safeguards.

PHYSICAL SAFEGUARDS STANDARDS

Physical safeguards are security measures to protect a healthcare provider's electronic information systems, related equipment, and the buildings housing the systems from natural and environmental hazards, and unauthorized intrusion. Healthcare providers must fulfill the following four standards. However, since most of the implementation specifications in this category are addressable, healthcare providers have flexibility in determining how to comply with the requirements as long as these are internally designed and developed as per the relevant SOP and published for all users to see and adhere to. Conformance to adherence may be delegated to the Privacy Officer detailed in the Data Ownership chapter above.

The required physical standards are:

- The facility access control standard, to limit actual physical access to electronic information systems and the facilities where they're located;
- The workstation use standard, to control the physical attributes of a specific workstation or group of workstations, to maximize security;
- The workstation security standard, to implement physical safeguards to deter the unauthorized access of a workstation; and
- The device and media controls standard, to control the movement of any electronic media containing ePHI from, to or within the facility.

226

Glossary

The various terms, including acronyms, are explained from a conceptual point and may not be the formal definitions.

ADSL (Asymmetric Digital Subscriber Line): A type of DSL that uses copper telephone lines to transmit data faster than a traditional modem. ADSL only works within short distances because it uses high frequencies with short signals.

Allergy List: This is a list of all the patient's allergies.

Allopathic, Allopathy: Defined as relating to or being a system of medicine that aims to combat disease by using remedies (as drugs or surgery) which produce effects that are different from or incompatible with those of the disease being treated

Ambulatory care: Any medical care delivered on an outpatient basis.

ANM: Auxiliary Nurse Midwife

Archetype: Basically an information model, it is a computable expression of a domain content model in the form of structured constraint statements, based on a reference (information) model. Within the openEHR paradigm, archetypes are based on the openEHR reference model. Archetypes are all expressed in the same formalism. In general, they are defined for wide re-use, however, they can be specialized to include local particularities. They can accommodate any number of natural languages and terminologies.

Artefact: An object made by a human being, typically one of cultural or historical interest. In healthcare IT context, an artefact is any item such as a document, file or drawing, etc. that is generated for use as a reference material or inside a system.

ASHA: Accredited Social Health Activist is usually a literate 25 – 45 year old married/ widowed/ divorced lady selected from the village itself and accountable to it and trained to work as an interface between the community and the public health system. This is position is one of the key components of the National Rural Health Mission aimed at providing every village in the country with a trained female community health activist

ATC: Anatomical Therapeutic Chemical Classification System, controlled by the WHO Collaborating Centre for Drug Statistics Methodology (WHOCC), is used for drug classification.

Authentication: The verification of the identity of a person or process.

Authorization: Any document designating any permission. Authorization or waiver of authorization for the use or disclosure of identifiable health information for research (among other activities) is required. The authorization must indicate if the health information used or disclosed is existing information and/or new information that will be created. The authorization form may be combined with the informed consent form, so that a patient need sign only one form. An authorization must include the following specific elements: a

description of what information will be used and disclosed and for what purposes; a description of any information that will not be disclosed, if applicable; a list of who will disclose the information and to whom it will be disclosed; an expiration date for the disclosure; a statement that the authorization can be revoked; a statement that disclosed information may be re-disclosed and no longer protected; a statement that if the individual does not provide an authorization, she/he may not be able to receive the intended treatment; the subject's signature and date.

AYUSH: Ayurveda, Yoga, Unani, Siddha and Homeopathy. Falls under the broad category of Indian Systems of Medicines and Homoeopathy (ISM&H) governed by Ministry of Health and Family Welfare, Government of India

[C]

CCD (Continuity of Care Document): A joint effort of HL7 International and ASTM. CCD fosters interoperability of clinical data by allowing physicians to send electronic medical information to other providers without loss of meaning and enabling improvement of patient care. CCD is an implementation guide for sharing Continuity of Care Record (CCR) patient summary data using the HL7 Version 3 Clinical Document Architecture (CDA), Release 2. It establishes a rich set of templates representing the typical sections of a summary record, and these same templates for vital signs, family history, plan of care, and so on can then be used for establishing interoperability across a wide range of clinical use cases.

CDT: Common Dental Terminology

Chain of Trust Agreement: A contract needed to extend the responsibility to protect health care data across a series of sub-contractual relationships.

Chief Complaint (CC), Reason for Consultation (RFC), Reason of Visit (ROV): for recording a patient's disease symptoms.

Client/Server Architecture: An information-transmission arrangement, in which a client program sends a request to a server. When the server receives the request, it disconnects from the client and processes the request. When the request is processed, the server reconnects to the client program and the information is transferred to the client. This usually implies that the server is located on site as opposed to the ASP (Application Server Provider) architecture.

Clinical Care Provider: Personnel or entities directly related to providing clinical care to patient.

Clinical Data Repository (CDR): A real-time database that consolidates data from a variety of clinical sources to present a unified view of a single patient. It is optimized to allow clinicians to retrieve data for a single patient rather than to identify a population of patients with common characteristics or to facilitate the management of a specific clinical department.

Clinical Decision Support System (CDSS): A clinical decision support system (CDSS) is software designed to aid clinicians in decision making by matching individual patient characteristics to computerized knowledge bases for the purpose of generating patient-specific assessments or recommendations.

224

GLOSSARY

Clinical Establishment: Clinical establishment means (1) a hospital, maternity home, nursing home, dispensary, clinic, sanatorium or an institution by whatever name called that offers services, facilities requiring diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognized system of medicine established and administered or maintained by any person or body of persons, whether incorporated or not; or (2) a place established as an independent entity or part of an establishment referred to above, in connection with the diagnosis or treatment of diseases where pathological, bacteriological, genetic, radiological, chemical, biological investigations or other diagnostic or investigative services with the aid of laboratory or other medical equipment, are usually carried on, established and administered or maintained by any person or body of persons, whether incorporated or not. (Clinical Establishment Act – CEA 2010)

Clinical Guidelines (Protocols): Clinical guidelines are recommendations based on the latest available evidence for the appropriate treatment and care of a patient's condition.

Clinical Messaging: Communication of clinical information within the electronic medical record to other healthcare personnel.

Coded Data: Data are separated from personal identifiers through use of a code. As long as a link exists, data are considered indirectly identifiable and not anonymous or anonymized.

Code Set: Any set of codes used to encode data elements, such as tables of terms, medical concepts, medical diagnostic codes, or medical procedure codes. This includes both the codes and their descriptions.

Coding: A mechanism for identifying and defining physicians' and hospitals' services. Coding provides universal definition and recognition of diagnoses, procedures and level of care. Coders usually work in medical records departments and coding is a function of billing. Medicare fraud investigators look closely at the medical record documentation, which supports codes and looks for consistency. Lack of consistency of documentation can earmark a record as "up-coded" which is considered fraud. A national certification exists for coding professionals and many compliance programs are raising standards of quality for their coding procedures.

Computer-Based Patient Record (CPR): A term for the process of replacing the traditional paper-based chart through automated electronic means; generally includes the collection of patient-specific information from various supplemental treatment systems, i.e., a day program and a personal care provider; its display in graphical format; and its storage for individual and aggregate purposes. CPR is also called "digital medical record" or "electronic medical record".

Computerized Patient Record (CPR): Also known as an EMR or EHR.A patient's past, present, and future clinical data stored in a server.

Computerized Physician Order Entry (CPOE): A system for physicians to electronically order labs, imaging and prescriptions

GLOSSARY

CPT (Current Procedural Terminology) Code: A recognizable five-digit number used to represent a service provided by a healthcare provider. It is a manual that assigns five digit codes to medical services and procedures to standardize claims processing and data analysis. The coding system for physicians' services developed by the CPT Editorial Panel of the American Medical Association.

[D]

Data Content: All the data elements and code sets inherent to a transaction, and not related to the format of the transaction.

Data: This is factual information (as measurements or statistics) used as a basis for reasoning, discussion, or calculation. It additionally points to the information output by a sensing device or organ that includes both useful and irrelevant or redundant information and must be processed to be meaningful.

Database Management System (DBMS): The separation of data from the computer application that allows entry or editing of data.

DICOM (Digital Imaging and Communications in Medicine): Digital Imaging and Communications in Medicine (DICOM) is a standard to define the connectivity and communication between medical imaging devices.

Disease Management: A type of product or service now being offered by many large pharmaceutical companies to get them into broader healthcare services. Bundles use of prescription drugs with physician and allied professionals, linked to large databases created by the pharmaceutical companies, to treat people with specific diseases. The claim is that this type of service provides higher quality of care at more reasonable price than alternative, presumably more fragmented, care. The development of such products by hugely capitalized companies should be the entire indicator necessary to convince a provider of how the healthcare market is changing. Competition is coming from every direction—other providers of all types, payers, employers who are developing their own in-house service systems, the drug companies.

Document Imaging: Is a process of converting paper documents into an electronic format usually through a scanning process.

Document Management: The Document Manager allows the medical institution to store vital patient documents such as X-Ray's, Paper Reports, and Lab Reports etc.

Documentation: The process of recording information.

DOHAD: Developmental Origins of Health and Diseases

Drug Formulary: Varying lists of prescription drugs approved by a given health plan for distribution to a covered person through specific pharmacies. Health plans often restrict or limit the type and number of medicines allowed for reimbursement by limiting the drug formulary list. The list of prescription drugs for which a particular employer or State Medicaid program will pay. Formularies are either "closed," including

222

only certain drugs or "open," including all drugs. Both types of formularies typically impose a cost scale requiring consumers to pay more for certain brands or types of drugs. See also Formulary.

Drug Formulary Database: This EMR feature is used for electronic prescribing, electronic medical record (EMR), and computerized physician order entry (CPOE) systems to present formulary status to the provider while during the prescribing decision.

DSM: Diagnostic and Statistical Manual for Mental Diseases

[E]

EDI: Acronym for Electronic Data Interchange. Electronic communication between two parties, generally for the filing of electronic claims to payers.

EDI Translator: Used in electronic claims and medical record transmissions, this is a software tool for accepting an EDI transmission and converting the data into another format, or for converting a non-EDI data file into an EDI format for transmission. See also Electronic Data Interchange.

EHR/EMR System Designer, Developer, Manufacturer, Vendor, Supplier, Retailer, Re-seller: Any entity that is involved in the design, development, testing, manufacturing, supplying, selling including re-selling of Electronic Health Records or Electronic Medical Records Systems as a whole or part thereof.

Electronic Data Interchange (EDI): The automated exchange of data and documents in a standardized format. In health care, some common uses of this technology include claims submission and payment, eligibility, and referral authorization. This refers to the exchange of routine business transactions from one computer to another in a standard format, using standard communications protocols.

Electronic Health Records (EHR): The one or more repositories, physically or virtually integrated, of information in computer processable form, relevant to the wellness, health and healthcare of an individual, capable of being stored and communicated securely and of being accessible by multiple authorized users, represented according to a standardized or commonly agreed logical information model. Its primary purpose is the support of life-long, effective, high quality and safe integrated healthcare. [ISO 18308:2011]

Electronic Medical Records (EMR): The EMR could be considered as special case of the EHR, restricted in scope to the medical domain or at least very much medically focused [ISO/TR 20514]. The Japanese Association of Healthcare Information Systems (JAHIS) has defined a five-level hierarchy of the EMR; Departmental EMR: contains a patient's medical information entered by a single hospital department (e.g. pathology, radiology, pharmacy); Inter-departmental EMR: contains a patient's medical information from two or more hospital departments; Hospital EMR: contains a patient's clinical information from a particular hospital; Inter-hospital EMR: contains a patient's medical information from two or more hospitals; EHR: longitudinal collection of health information from all sources. [Classification of EMR systems, JAHIS, V1.1, Mar 1996]

Electronic Protected Health Information (ePHI): Electronic Protected Health Information (ePHI) is any protected health information (PHI) that is created, stored, transmitted, or received electronically. Electronic

protected health information includes any medium used to store, transmit, or receive PHI electronically. The following and any future technologies used for accessing, transmitting, or receiving PHI electronically are covered. Media containing data at rest (data storage) like personal computers with internal hard drives used at work, home, or traveling, external portable hard drives, including iPods and similar devices, magnetic tape, removable storage devices, such as USB memory sticks, CDs, DVDs, and floppy disks, PDAs and smartphones and data in transit, via wireless, Ethernet, modem, DSL, or cable network connections, Email, File transfer. (For Protected Health Information – PHI, please see below)

Encounter: A clinical encounter is defined by ASTM as "(1) an instance of direct provider/practitioner to patient interaction, regardless of the setting, between a patient and a practitioner vested with primary responsibility for diagnosing, evaluating or treating the patient's condition, or both, or providing social worker services. (2) A contact between a patient and a practitioner who has primary responsibility for assessing and treating the patient at a given contact, exercising independent judgment." Encounter serves as a focal point linking clinical, administrative and financial information. Encounters occur in many different settings -- ambulatory care, inpatient care, emergency care, home health care, field and virtual (telemedicine). [http://www.ncvhs.hhs.gov/040127p1.htm]

Episode: An episode of care consists of all clinically related services for one patient for a discrete diagnostic condition from the onset of symptoms until the treatment is complete [http://www.ncmedsoc.org/non_members/pai/PAI-FinalWorkbookforVideo.pdf] Thus, for every new problem or set of problems that a person visits his clinical care provider, it is considered a new episode. Within that episode the patient will have one or many encounters with his clinical care providers till the treatment for that episode is complete. Even before the resolution of an episode, the person may have a new episode that is considered as a distinctly separate event altogether. Thus, there may be none, one or several ongoing active episodes. All resolved episodes are considered inactive. Hence they become part of the patient's past history. A notable point here is that all chronic diseases are considered active and may never get resolved during the life-time of the person, e.g., diabetes mellitus, hypertension, etc.

EPR: Broadly defined, a personal health record is the documentation of any form of patient information–including medical history, medicines, allergies, visit history, or vaccinations–that patients themselves may view, carry, amend, annotate, or maintain. Today, when we refer to PHRs, we typically mean an online personal health record–which may variously be referred to as an ePHR, an Internet PHR, an Internet medical record, or a consumer Internet Medical Record (CIMR). Generally, such records are maintained in a secure and confidential environment, allowing only the individual, or people authorized by the individual, to access the medical information. Not all electronic PHRs are Internet PHRs. PC-based PHRs may be set up to capture medical information offline.

Evidence Based Medicine: Evidence-based medicine (EBM) is the integration of best research evidence with clinical expertise to aid in the diagnosis and management of patients.

[F]

220

Family History: A list of the patient's family medical history including the chronic medical problems of parents, siblings, grandparents, etc.

FHIR: Fast Health Interoperable Resources, the newest version from HL7 org for messaging.

Formatting and Protocol Standards: Data exchange standards which are needed between CPR systems, as well as CPT and other provider systems, to ensure uniformity in methods for data collection, data storage and data presentation. Proactive providers are current in their knowledge of these standards and work to ensure their information systems conform to the standards.

Formulary: An approved list of prescription drugs; a list of selected pharmaceuticals and their appropriate dosages felt to be the most useful and cost effective for patient care. Organizations often develop a formulary under the aegis of a pharmacy and therapeutics committee. In HMOs, physicians are often required to prescribe from the formulary. See also Drug Formulary.

[G]

Growth Chart: A feature for a Primary Care or EMR that can be used for pediatric patients. Age, height, weight, and head measurements can be entered over the patient's lifetime, and the feature creates a line graph.

[H]

Health Care Operations: Institutional activities that is necessary to maintain and monitor the operations of the institution. Examples include but are not limited to: conducting quality assessment and improvement activities; developing clinical guidelines; case management; reviewing the competence or qualifications of health care professionals; education and training of students, trainees and practitioners; fraud and abuse programs; business planning and management; and customer service. Under the HIPAA Privacy Rule, these are allowable uses and disclosures of identifiable information "without specific authorization." Research is not considered part of health care operations.

Health Care, Healthcare: Care, services, and supplies related to the health of an individual. Health care includes preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, among other services. Healthcare also includes the sale and dispensing of prescription drugs or devices.

Health Information: Information in any form (oral, written or otherwise) that relates to the past, present or future physical or mental health of an individual. That information could be created or received by a health care provider, a health plan, a public health authority, an employer, a life insurer, a school, a university or a health care clearinghouse. All health information is protected by state and federal confidentiality laws and by HIPAA privacy rules.

Health Level Seven (HL7): A data interchange protocol for health care computer applications that simplifies the ability of different vendor-supplied IS systems to interconnect. Although not a software program in itself, HL7 requires that each healthcare software vendor program HL7 interfaces for its products. The organization is one of the American National Standards Institute accredited Standard Developing

219

GLOSSARY

Organization (SDO) - Health Level 7 domain is the standards for electronic interchange of clinical, financial and administrative info among healthcare oriented computer systems. Is a not-for-profit volunteer organization. It develops specifications, most widely used is the messaging standard that enables disparate health care applications to exchange key sets of clinical and administrative data. It promotes the use of standards within and among healthcare organizations to increase the effectiveness and efficiency of healthcare delivery. It is an international community of healthcare subject matter experts and information scientists collaborating to create standards for the exchange, management and integration of electronic healthcare information.

Health: The state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity. It is recognized, however, that health has many dimensions (anatomical, physiological, and mental) and is largely culturally defined. The relative importance of various disabilities will differ depending upon the cultural milieu and the role of the affected individual in that culture. Most attempts at measurement have been assessed in terms or morbidity and mortality.

Healthcare provider: A health care provider is an individual or an institution that provides preventive, curative, promotional or rehabilitative health care services in a systematic way to individuals, families or communities. An individual health care provider may be a health care professional, an allied health professional, a community health worker, any or other person trained and knowledgeable in medicine, nursing or other allied health professions, or public/community health workers like , ASHA, ANM, midwives, paramedical staff, OT/lab/radio-diagnostic technicians, etc. An institution will include hospitals, clinics, primary care centers and other service delivery points of health care individual clinics, polyclinics, diagnostic centers, etc., i.e., any place where a medical record is generated during a patient-care provider encounter (in conformance to CEA 2010 – please refer to Clinical Establishment item above). It must be noted that any person solely performing non-clinical work is not a care provider.

Healthcare Service Provider (HSP): see Healthcare provider

History of Present Illness (HPI): The HPI is the history of the patient's chief complaint.

Human Subject: Refers to a living subject participating in research about whom directly or indirectly identifiable health information or data are obtained or created.

Hybrid Record: Term used for when a provider uses a combination of paper and electronic medical records during the transition phase to EMR.

[I]

Independent Software Vendor (ISV): A company specializing in making or selling software products that runs on one or more computer hardware or operating system platforms.

Immunization: A complete list of all immunizations that the patient has had.

Informatics: The application of computer technology to the management of information.

218

GLOSSARY

Integration: Integration allows for secure communication between enterprise applications.

Interface: A means of communication between two computer systems, two software applications or two modules. Real time interface is a key element in healthcare information systems due to the need to access patient care information and financial information instantaneously and comprehensively. Such real time communication is the key to managing health care in a cost effective manner because it provides the necessary decision-making information for clinicians, providers, other stakeholders, etc.

International Classification of Diseases: This is the universal coding method used to document the incidence of disease, injury, mortality and illness. A diagnosis and procedure classification system designed to facilitate collection of uniform and comparable health information. The ICD-9-CM was issued in 1979. This system is used to group patients into DRGs, prepare hospital and physician billings and prepare cost reports. Classification of disease by diagnosis codified into six-digit numbers. See also coding.

International Health Terminology Standards Development Organization (IHTSDO): Denmark-based organization that maintains and licenses SNOMED codes worldwide.

Interoperability: The capability to provide successful communication between end-users across a mixed environment of different domains, networks, facilities and equipment.

ISP: Internet Service Provider

ISV (Independent Software Vendor): An independent software vendor (ISV) is a company specializing in making or selling software, designed for mass or niche markets. This typically applies for application-specific or embedded software, from other software producers.

[J]

J-Codes: A subset of the HCPCS Level II code set with a high-order value of "J" that has been used to identify certain drugs and other items.

[L]

LAN (Local Area Network): A LAN supplies networking capability to a group of computers in close proximity to each other such as in an office building, a school, or a home.

Legacy System Integration: The integration of data between a legacy system and some other software program most commonly using HL-7 standards.

Legacy Systems: Computer applications, both hardware and software, which have been inherited through previous acquisition and installation. Most often, these systems run business applications that are not integrated with each other. Newer systems which stress open design and distributed processing capacity are gradually replacing such systems.

Length of Stay (LOS): The duration of an episode of care for a covered person. The number of days an individual stays in a hospital or inpatient facility. May also be reviewed as Average Length of Stay (ALOS).

217

LEPR (Longitudinal Patient Record): Longitudinal Patient Record is an EHR that includes all healthcare information from all sources.

[M]

Management Information System (MIS): The common term for the computer hardware and software that provides the support of managing the plan.

Master Patient / Member Index: An index or file with a unique identifier for each patient or member that serves as a key to a patient's or member's health record.

Maximum Defined Data Set: All of the required data elements for a particular standard based on a specific implementation specification. An entity creating a transaction is free to include whatever data any receiver might want or need. The recipient is free to ignore any portion of the data that is not needed to conduct their part of the associated business transaction, unless the inessential data is needed for coordination of benefits.

MCI: Medical Council of India

Medical Code Sets: Codes that characterize a medical condition or treatment. These code sets are usually maintained by professional societies and public health organizations. Compare to administrative code sets.

Medical Informatics: Medical informatics is the systematic study, or science, of the identification, collection, storage, communication, retrieval, and analysis of data about medical care services to improve decisions made by physicians and managers of health care organizations. Medical informatics will be as important to physicians and medical managers as the rules of financial accounting are to auditors.

Medical Management Information System (MMIS): A data system that allows payers and purchasers to track health care expenditure and utilization patterns. It may also be referred to as Health Information System (HIS), Health Information Management (HIM) or Information System (IS). See also Electronic Medical Record (EMR).

Metadata and Date Standard (MDDS) – A set of data elements and their specification for use in certain domain, such as health, e-governance.

MIMS: Monthly Index of Medical Specialties

Minimum Data Set: The minimum set of data elements that must be captured, stored, made available for retrieval, presentation, relay and sharing by an EHR system. It comprises of all of the essential data elements required for implementation. An entity creating a transaction must include the mandatory data elements at all times and is free to exclude optional data elements. The entity is free to additionally include whatever other data elements that any receiver might want or need. The recipient is free to ignore any portion of the data that is not mandatory and is further free to ignore any other portion of the data that is not needed to conduct their part of the associated transaction, unless required by sender, intermediaries or receiver. This minimum data set represents the most common data, and system designers are at liberty to add to it as they deem necessary to enrich or enhance their EHR systems.

216

Modifier: Additional character of a code added to an existing code that is used to help in extending or localization of the existing code.

[N]

NANDA: North American Nursing Diagnosis Association

National Council for Prescription Drug Programs: An ANSI-accredited group that maintains a number of standard formats for use by the retail pharmacy industry.

NEMA: The National Electrical Manufacturers Association (NEMA) is the association of electrical equipment and medical imaging manufacturers, founded in 1926 and headquartered in Rosslyn, Virginia.

Non-Participating Physician (or Provider): A provider, doctor or hospital that does not sign a contract to participate in a health plan, usually which requires reduced rates from the provider. In the Medicare Program, this refers to providers who are therefore not obligated to accept assignment on all Medicare claims. In commercial plans, non-participating providers are also called out of network providers or out of plan providers. If a beneficiary receives service from an out of network provider, the health plan (other than Medicare) will pay for the service at a reduced rate or will not pay at all.

[O]

Open Access: A term describing a member's ability to self-refer for specialty care. Open access arrangements allow a member to see a participating provider without a referral from another doctor. Health plan members' abilities, rights or invitation to self refer for specialty care. Also called Open Panel.

openEHR: openEHR is an open standard specification in health informatics that describes the management and storage, retrieval and exchange of health data in electronic health records (EHRs). In openEHR, all health data for a person is stored in a "one lifetime", vendor-independent, person-centered EHR. Maintained by the openEHR Foundation, these are based on a combination of 15 years of European and Australian research and development into EHRs and new paradigms, including what has become known as the archetype methodology for specification of content and include information and service models for the EHR, demographics, clinical workflow and archetypes. They are designed to be the basis of a medico-legally sound, distributed, versioned EHR infrastructure.

OR: Operating Room – synonymous to OT as below

OT: Operation Theatre

OTC: Over the counter (drugs). Refers to those drugs that are available off the shelf without any prescription or advise from a registered medical practitioner

Outcome: A clinical outcome is the "change in the health of an individual, group of people or population which is attributable to an intervention or series of interventions". (Taken from: Frommer, Michael; Rubin, George; Lyle, David (1992)."The NSW Health Outcomes program". New South Wales Public Health Bulletin 3: 135. doi:10.1071/NB92067)

GLOSSARY

Outpatient Care: Care given a person who is not bedridden. It is also called ambulatory care. Many surgeries and treatments are now provided on an outpatient basis, while previously they had been considered reason for inpatient hospitalization. Some say this is the fastest growing segment of healthcare

[P]

Participating Physician: A primary care physician in practice in the payer's managed care service area who has entered into a contract.

Past History: A list of a patient's past health problems, surgeries and specialists.

Patient Demographics: All patient's pertinent information such as first and last name, SSN, DOB, insurance, etc.

Patient Portal: A secure web-based system that allows a patient to register for an appointment, schedule an appointment, request prescription refills, send and receive secure patient-physician messages, view lab results, pay their bills electronically, access physician directories.

Patient: A person who is under medical care or treatment

PC Based: A program designed to run on an individual PC. This typically means data is not shared in real time among other PCs (users).

PCP: Primary care physician who often acts as the primary gatekeeper in health plans. That is, often the PCP must approval referrals to specialists. Particularly in HMOs and some PPOs, all members must choose or are assigned a PCP.

PHR: A personal health record or PHR is typically a health record that is initiated and maintained by an individual. An ideal PHR would provide a complete and accurate summary of the health and medical history of an individual by gathering data from many sources and making this information accessible online.

Picture Archive Communication System (PACS): Used by radiology and diagnostic imaging organizations to electronically manage information and images

Practice Parameters, Practice Guidelines: Systematically developed statements to standardize care and to assist in practitioner and patient decisions about the appropriate health care for specific circumstances. Practice guidelines are usually developed through a process that combines scientific evidence of effectiveness with expert opinion. Practice guidelines are also referred to as clinical criteria, protocols, algorithms, review criteria, and guidelines. The American Medical Association defines practice parameters as strategies for patient management, developed to assist physicians in clinical decision-making. Practice parameters may also be referred to as practice options, practice guidelines, practice policies, or practice standards.

Prescription Drug: Drug that the law says can only be obtained by prescription.

214

Primary Care Physician: A "generalist" such as a family practitioner, pediatrician, internist, or obstetrician. In a managed care organization, a primary care physician is accountable for the total health services of enrollees including referrals, procedures and hospitalization. Also see Primary Care Provider.

Primary Care Provider: The provider that serves as the initial interface between the member and the medical care system. The PCP is usually a physician, selected by the member upon enrollment, who is trained in one of the primary care specialties who treats and is responsible for coordinating the treatment of members assigned to his/her plan.

Primary Care: Basic or general health care usually rendered by general practitioners, family practitioners, internists, obstetricians and pediatricians who are often referred to as primary care practitioners or PCPs. Professional and related services administered by an internist, family practitioner, obstetrician-gynecologist or pediatrician in an ambulatory setting, with referral to secondary care specialists, as necessary.

Principal Diagnosis: The medical condition that is ultimately determined to have caused a patient's admission to the hospital. The principal diagnosis is used to assign every patient to a diagnosis related group. This diagnosis may differ from the admitting and major diagnoses.

Privacy Standards: The Privacy standards restrict the use & disclosure of individually identifiable health information. Privacy standard applies to all protected health information may it is in physical or electronic form.

Privacy: Privacy means an individual's interest in limiting who has access to personal health care information. Specific patient authorization is required for use and disclosure of clinical notes. As per Fernando & Dawson, 2009, privacy is control of access to private information avoiding certain kinds of embarrassment and can be shared or not shared with others; Only authorized (by the patient) people can view the recorded data or part thereof

Progress Note: The documentation of a patient visit or encounter including all or part of the SOAP format.

Protected health information (PHI): Any individually identifiable information whether oral or recorded in any form or medium that is created, or received by a health care provider, health plan or health care Healthcare provider and relates to past, present, or future physical or mental health conditions of an individual; the provision of health care to the individual; or past, present, or future payment for health care to an individual.

[R]

Real Time: The instantaneous sharing of data among a user group. It is common to a client/server database configuration.

Reference Model (RM):

Referral: Some insurance companies require that on specific plans a referral must be obtained for certain procedures or visits to specialists. The referral is acquired by the primary care physician (PCP) by

contacting the insurance company by phone or mail. This is a request for the service. The referral consists of an authorization code, a number of visits allowed (if applicable) and an expiration date.

Referring Provider: is the provider that referred the patient to a specialist or for a specific procedure.

Regenstrief: The Regenstrief Institute is an international non-profit medical research organization associated with Indiana University. It produces and maintains LOINC codes.

Relational Database: A database program that stores data in a manner similar to Excel, with the difference being the data elements are related (linked) to each other.

Remote Access: Data travels through a private, protected passage via the Internet, allowing healthcare providers to access from home or another practice location and allows EMR vendor to perform system maintenance off-site

Rendering/Performing Provider: The provider actually treating the patient.

Roles and Access Levels: The role and access level of the user needs to be determined and set by the system administrator. The role determines the access level. While roles may be such as system administrator, medical doctor, registered nurse, medical student, medical assistant, nurse assistant, ancillary nurse, health worker, Anganwadi worker (grass-root health worker), etc., the access levels may include viewing only, viewing/adding/editing only, viewing/adding/editing/deleting, all allowed etc. These need to be set out clearly in the SOP of the facility.

ROS (Review of Systems): A series of questions related to the system(s) that the patient is having complaints about (i.e. respiratory for cold symptoms).

RxNorm: RxNorm is the name of a US-specific terminology in medicine that contains all medications available on US market; it provides normalized names for clinical drugs and links its names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software.

[S]

Secondary Care: Services provided by medical specialists who generally do not have first contact with patients (e.g., cardiologist, urologists, dermatologists). In the U.S., however, there has been a trend toward self-referral by patients for these services, rather than referral by primary care providers. This is quite different from the practice in England, for example, where all patients must first seek care from primary care providers and are then referred to secondary and/or tertiary providers, as needed.

Security Standards: The Security Standards require measures to protect the confidentiality, integrity and availability of e-PHI while it's being stored & exchanged. The security standard applies to all electronic PHI.

Security: This refers to the methods and techniques adopted to protect privacy and are a defense mechanism from any attack (Hong et al., 2004)

212

SNOMED: Systemized Nomenclature of Medicine Clinical Terms is the universal health care terminology. It is comprehensive and covers procedures, diseases, and clinical data. SNOMED CT helps to structure and computerize the medical record. It allows for a consistent way of indexing, storing, retrieving and aggregating clinical data across sites of care (i.e. hospitals, doctors offices) and specialties. By standardizing the terminology, the variability in the way data is captured, encoded and used for clinical care of patients and research is reduced. Allows for more accurate reporting of data. It is currently available in English, Spanish and German.

Social History: A description of a patient's social habits and history including marital status, alcohol and drug use and exercise habits.

Solo Practice, Solo Practitioner: A physician who practices alone or with others but does not pool income or expenses. This form of practice is becoming increasingly less common as physicians band together for contracting, overhead costs and risk sharing.

SOP: Standard operating procedures or protocols

SQL: Structured Query Language – is a computer language aimed to store, manipulate and retrieve data stored in relational databases.

SDO: Standards Development Organization – an organization responsible for development and maintenance of a standard or several, usually run on a not-for-profit basis.

Subjective: Section in a progress note where a patient's account of their current problem is documented. Consists of chief complaint, HPI and ROS.

Sx: Abbreviation for symptoms

[T]

T1, T3 line: A high-speed internet connection provided via telephone lines often used by businesses needing internet connection speeds greater than DSL/Cable.

Therapeutic Alternatives: Strong Drug products that provide the same pharmacological or chemical effect in equivalent doses. Also see Drug Formulary.

TPA: Third Party Administrator

Treatment Episode: The period of treatment between admission and discharge from a modality, e.g., inpatient, residential, partial hospitalization, and outpatient, or the period of time between the first procedure and last procedure on an outpatient basis for a given diagnosis. Many healthcare statistics and profiles use this unit as a base for comparisons.

Treatment: The provision of health care by one or more health care providers. Treatment includes any consultation, referral or other exchanges of information to manage a patient's care.

GLOSSARY

[V]

Vital Statistics: Statistics relating to births (natality), deaths (mortality), marriages, health, and disease (morbidity). Vital statistics for the United States are published by the National Center for Health Statistics. Vital statistics can be obtained from CDC, state health departments, county health departments and other agencies. An individual patient's vital statistics in a health care setting may also refer simply to blood pressure, temperature, height and weight, etc.

VPN: Virtual Private Network – A VPN "tunnel" is a secure connection, typically firewall to firewall that provides for remote access to your data server.

[W]

WHO: The World Health Organization is a specialized agency of the United Nations that is concerned with international public health.

[X]

XML (Extensible Markup Language): Used for defining data elements on a Web page and communication between two business systems. Example: Standard messaging system for and EMR to integrate with another software such as a practice management or drug formulary database.

210

CONTACT INFORMATION

Contact Information

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Department of Health & Family Welfare
Ministry of Health & Family Welfare
Government of India
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Implementation specific queries may be referred to:
National Release Center (NRC)
VC&BA, Centre for Development of Advanced Computing (C-DAC)
Savitribai Phule Pune University Campus
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Pune – 411007
Email: nrc-help@cdac.in
http://www.snomedctnrc.in

EHR Standards
—
Revisions Undertaken

Baljit Singh Bedi
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& Chair, Sub-Group, Interoperability;
Chair, FICCI EHR Subcommittee
Past President , Telemedicine Society of India(TSI) &
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Presentation to EHR Revision
Committee-MoHFW-14 Dec 2015

Background - Understanding Information and Communication Technologies (ICTs)

- Healthcare area is highly Data dependent. Power of ICTs lies in its capacity to effectively
- Access data
- Store data
- Analyze data
- Transmit data
- Predictive Analytics

Utilizing this capability of ICTs has the potential to significantly contribute in preventive care, improving delivery , disease control , medical education and training, health management and health research

202

Standardisation- Indian Initiative

- Initiative in suggesting a **Framework for Information Technology Infrastructure for Health(ITIH) in India** (First effort for suggesting a Standard EHR for India)
- National efforts in proposing **Recommendations on Guidelines, Standards & Practices For Telemedicine In India**
- **National Knowledge Commission's India Health Information Network Development (I-HIND)**
- ***EHR Standardization Initiative of MoH&FW***

EMR Standards Committee

- Ministry of Health & Family Welfare (MoH&FW), Govt. of India constituted a Committee of Experts for Development of Standards on EMR in Sept 2010 under Chairmanship of Additional Secretary &DG,CGHS, MoH&FW
- Objective of above Committee to recommend a set of EMR Standards for India to be followed by both public & private healthcare provider
- Procedure for continuous upgradation

Activities Undertaken

- EMR Standardisation Committee set up Sub-Groups related to Standards – Terminology and coding standards, Data connectivity- including H/W,S/W & Interoperability, and Data ownership-Data protection& including security and legal aspects in October 2010
- The EHR standards were a result of the deliberations of the EMR Standards Committee & Subgroups and consolidation by the Sub-committee under FICCI of the public comments on the draft report put up by MoHFW, GoI in their website in May 2013 and deliberations thereof, finalized in August, 2013

Activities Undertaken

- Notified in September, 2013 on MoH&FW Website
- EHR Review Committee formed in August 2015 to review the approved standards and redraft the same with the aim of bringing it in line with current knowledge and understanding
- Incorporate changes, as deemed fit, in view of India becoming a member of IHTSDO in April 2014 and SNOMED CT now being available to all in India

Major Revision Points

- Demography data to include person detail and MDDS from DeitY to be used for person details.
- Identifier standards and guidelines added to enable sharing of record across establishments.
- SNOMED CT is clarified as being the primary terminology for all parts of a clinical record, now that India is member country of IHTSDO and SNOMED CT is available to all India entities for free.

Major Revision Points

- LOINC is now recommended for test, measurement and observations. Mapping with SNOMED CT is also mentioned.
- WHO Family of International Classification (that includes ICD, ICF, and few others) is now recommended for classification and reporting.
- Implementation guidelines sections added for each of the standards to help ISVs in implementing them by providing sufficient clarity regarding them.
- Minimum Data Set section has been removed as it is now unnecessary and was in non-conformance with the recommended ISO 13606 standard and archetype based structural composition.

Major Revision Points-contd.

- Security and Privacy standards are indicated with clarity.
- List of supporting and complementing ISO standards streamlined.
- BIS, ISO and other SDOs are now mentioned for selection of standards not provided for specifically.
- HL7 messaging standards have been streamlined to provide greater clarity.

Major Revision Points-contd.

- Scanned document standards have been introduced.
- E-prescription standards have been introduced.
- Device integration standards have been specified.
- Guidelines for hardware/software and data ownership have been revised to provide greater clarity.

Minor Revision Points

- Standards at a Glance section added to provide tabular list of standards and their intended applicable domain.
- Duplicates removed.
- Glossary streamlined.
- Layout and general document format changed to provide improved readability.

Standards At A Glance

Type	Standard Name	Intended Purpose
Identification & Demographics	ISO/TS 22220:2011 Health Informatics – Identification of Subjects of Health Care	Basic identity details of patient
	MDDS – Demographic (Person Identification and Land Region Codification) version 1.1	Complete demographic for interoperability with E-Governance systems
Patient Identifiers	UIDAI Aadhaar	Preferable identifier where available
	Local Identifier	Identifier given within institution / clinic / lab
	Government Issued Photo Identity Card Number	Identifier in conjunction with local in absence of Aadhaar

Standards At A Glance-contd

Type	Standard Name	Intended Purpose
Architecture Requirements	ISO 18308:2011 Health Informatics – Requirements for an Electronic Health Record Architecture	System architectural requirements
Functional Requirements	ISO/HL7 10781;2015 Health Informatics - HL7 Electronic Health Records-System Functional Model Release 2 (EHR FM)	System functional requirements
Reference Model and Composition	ISO 13940 Health informatics - System of Concepts to Support Continuity of Care	Concepts for care, actors, activities, processes, etc.
	ISO 13606 Health informatics - Electronic Health Record Communication (Part 1 through 3)	Information model architecture and communication
	openEHR Foundation Models Release 1.0.2	Structural definition and composition

Standards At A Glance-contd.

Type	Standard Name	Intended Purpose
Terminology	SNOMED Clinical Terms (SNOMED CT)	Primary terminology
Coding System	Logical Observation Identifiers Names and Codes (LOINC)	Test, measurement, observations
	WHO Family of International Classifications (WHO-FIC) including ICD, ICF, ICHI, ICD-O	Classification and reporting

Standards At A Glance-contd.

Type	**Standard Name**	**Intended Purpose**
Imaging	Digital Imaging and Communications in Medicine (DICOM) PS3.0-2015	Image, waveform, audio/video
Scanned or Captured Records	JPEG lossy (or lossless) with size and resolution not less than 1024px x 768px at 300dpi	Image capture format
	ISO/IEC 14496 - Coding of Audio-Visual Objects	Audio/Video capture format
	ISO 19005-1 Document Management - Electronic Document File Format for Long-Term Preservation - Part 1: Use of PDF 1.4 (PDF/A-1)	Scanned documents format

Standards At A Glance-contd

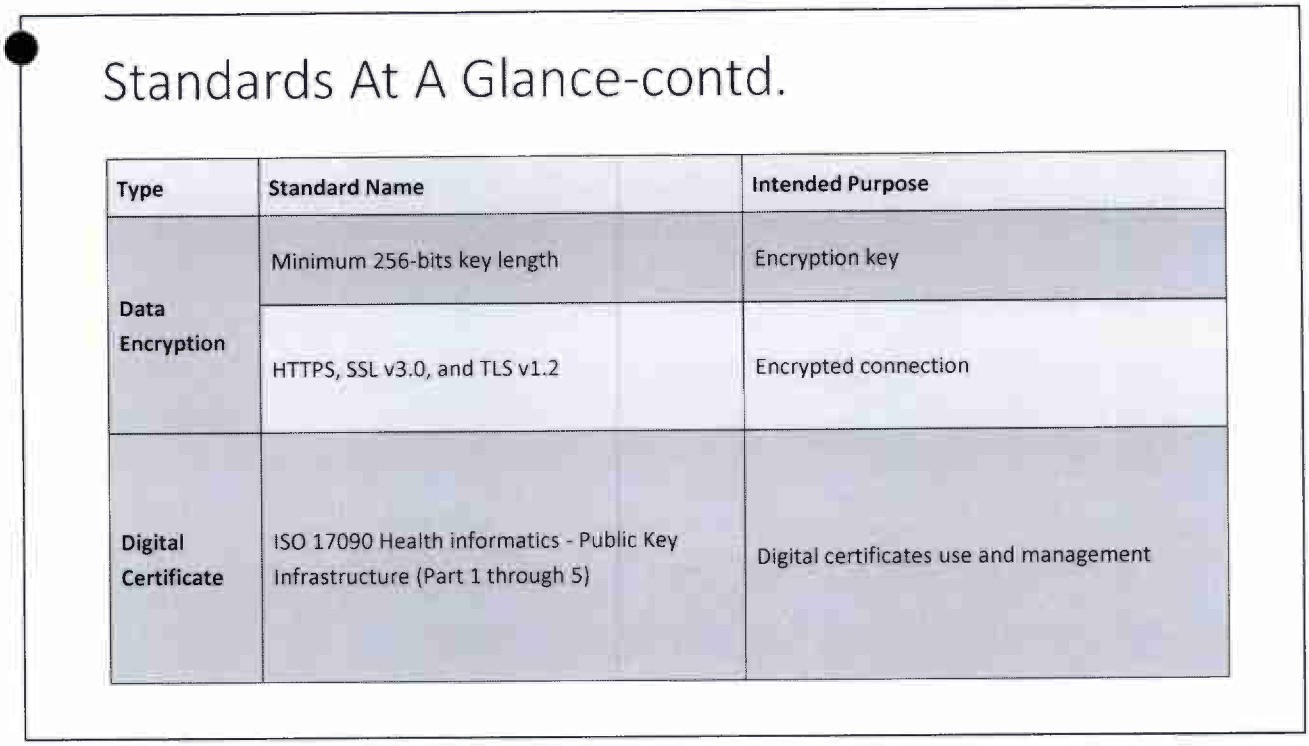
Type	**Standard Name**	**Intended Purpose**
Data Exchange	ANSI/HL7 V2.8.2-2015 HL7 Standard Version 2.8.2 - An Application Protocol for Electronic Data Exchange in Healthcare Environments	Event/Message exchange
	ASTM/HL7 CCD Release 1 (basis standard ISO/HL7 27932:2009)	Summary Records exchange
	ISO 13606-5:2010 Health informatics - Electronic Health Record Communication - Part 5: Interface Specification	EHR archetypes exchange [Also, refer to openEHR Service Model specification]
	DICOM PS3.0-2015 (using DIMSE services & Part-10 media/files)	Imaging/Waveform Exchange

Standards At A Glance-contd.

Type	Standard Name	Intended Purpose
Other Relevant Standards	Bureau of Indian Standards and its MHD-17 Committee	Standards Development Organizations (SDOs)
	ISO TC 215 set of standards	
	IEEE/NEMA/CE standards for physical systems and interfaces	
Discharge/ Treatment Summary	Medical Council of India (MCI) under regulation 3.1 of Ethics	Composition as prescribed
E-Prescription	Pharmacy Practice Regulations, 2015 Notification No. 14-148/ 2012- PCI as specified by Pharmacy Council of India	Composition as prescribed
Personal Healthcare and medical Device Interface	IEEE 11073 health informatics standards and related ISO standards for medical devices	Device interfacing

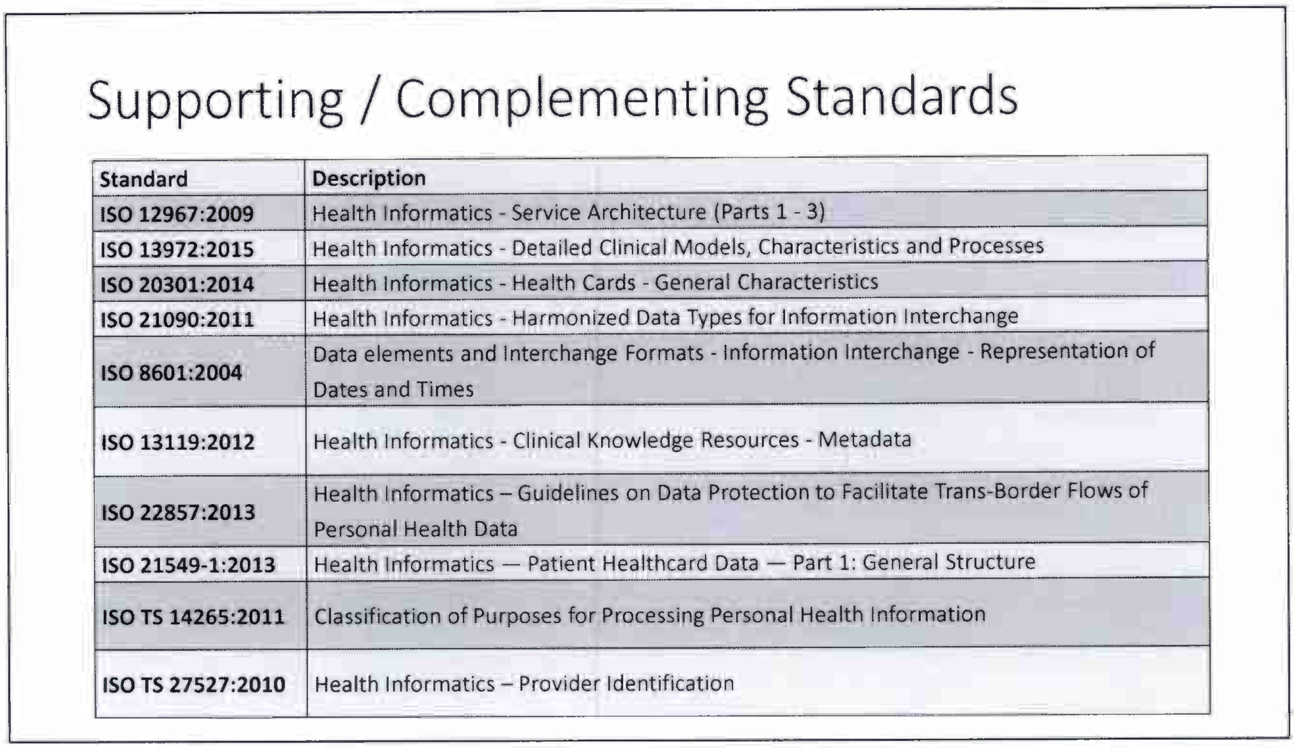
Standards At A Glance-contd

Type	Standard Name	Intended Purpose
Data Privacy and Security	ISO/TS 14441:2013 Health Informatics – Security & Privacy Requirements of EHR Systems for Use in Conformity Assessment	Basis security and privacy requirements
Information Security Management	ISO/DIS 27799 Health informatics - Information Security Management in Health using ISO/IEC 27002	Overall information security management
Privilege Management and Access Control	ISO 22600:2014 Health informatics - Privilege Management and Access Control (Part 1 through 3)	Access control
Audit Trail and Logs	ISO 27789:2013 Health informatics - Audit trails for Electronic Health Records	Audit trail
Data Integrity	Secure Hash Algorithm (SHA) used must be SHA-256 or higher	Data Hashing



Standards At A Glance-contd.

Type	Standard Name	Intended Purpose
Data Encryption	Minimum 256-bits key length	Encryption key
	HTTPS, SSL v3.0, and TLS v1.2	Encrypted connection
Digital Certificate	ISO 17090 Health informatics - Public Key Infrastructure (Part 1 through 5)	Digital certificates use and management



Supporting / Complementing Standards

Standard	Description
ISO 12967:2009	Health Informatics - Service Architecture (Parts 1 - 3)
ISO 13972:2015	Health Informatics - Detailed Clinical Models, Characteristics and Processes
ISO 20301:2014	Health Informatics - Health Cards - General Characteristics
ISO 21090:2011	Health Informatics - Harmonized Data Types for Information Interchange
ISO 8601:2004	Data elements and Interchange Formats - Information Interchange - Representation of Dates and Times
ISO 13119:2012	Health Informatics - Clinical Knowledge Resources - Metadata
ISO 22857:2013	Health Informatics – Guidelines on Data Protection to Facilitate Trans-Border Flows of Personal Health Data
ISO 21549-1:2013	Health Informatics — Patient Healthcard Data — Part 1: General Structure
ISO TS 14265:2011	Classification of Purposes for Processing Personal Health Information
ISO TS 27527:2010	Health Informatics – Provider Identification

199

New Additions

- SNOMED CT to be the primary terminology code system for all parts of a clinical record
- LOINC and ICD is to be used as per requirement like reporting, epidemiological analysis, etc.
- Standards for scanned documents have been introduced
- Duplications and conflicts resolved, namely
  - Minimum Data Set section has been removed as it conflicted with ISO 13606 requirements
- BIS-mandated ISO standards have been incorporated

Recommendations (to the committee)

- The revised EHR Standards be adopted and approved after deliberation as National EHR Standards
- These EHR Standards be forwarded to Bureau of Indian Standards by MoH&FW, Government of India for consideration of adopting the same as Indian Standards

Thank you

bedi11@yahoo.com

Subject: **Minutes of the Second Meeting of the Electronic Health Record (EHR) Standards Review Committee held on 14th December, 2015**
Date: 01/06/16 05:28 PM
From: "Amit Kumar" <amit.k89@gov.in>
To: sunil.sharma62@gov.in, dir.ehealth@gmail.com, sunita.dhaundiyal@nic.in, supten@nihfw.org, supten@gmail.com, sbbhattacharyya@gmail.com, gaurs@cdac.in, bedi11@yahoo.com, sunil.bhushan@gov.in, drkaranvir_s@apollohospitals.com, narwalr@who.int, godarab@who.int, shobha.mishra@ficci.com, quasim.ali@ficci.com, dr.amitmishra@gmail.com, chandrasens@deloitte.com, nimalhotra@deloitte.com, bhanuprakash@deloitte.com
Cc: asfnd.kb@gmail.com

Minutes of the Second Meeting of the EHR Standards... (1.1MB)
Revised EHR Standards-Presentation-MoHFW-14-12-201... (450kB)

Sir,

The second meeting of 'EHR Standards Review Committee' was held on 14th December, 2015 at 3:30 P.M. in Room No.406, A –Wing, Nirman Bhawan, Ministry of Health & Family Welfare under the Chairmanship of Shri Sunil Sharma, JS (eGovernance).

Please find attached minutes of the same.

Regards
Amit Kumar
Assistant Director (eGovernance)
Ministry of Health & Family Welfare
Room No. 425C
Nirman Bhawan
New Delhi – 110 011
Tel: 011 – 2306 2263
Mobile: 9582861973

Department of Health & Family Welfare
e-Governance Division
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96

Subject: Minutes of the Second Meeting of the Electronic Health Record (EHR) Standards Review Committee held on 14thDecember, 2015

The second meeting of 'EHR Standards Review Committee' was held on 14th December, 2015 at 3:30 P.M. in the Room No.406, A –Wing, Nirman Bhawan, Ministry of Health & Family Welfare under the Chairmanship of Shri Sunil Sharma, JS (eGovernance). Representatives from WHO attended the meeting as special invitees. The list of participants is placed at **Annexure - A**.

2. Shri Sunil Sharma, JS(eGov) welcomed the participants and briefed about the overall objective/purpose of EHR Standards which had been notified by MoHFW in August 2013 after detailed deliberations with various stakeholder groups. He thereafter asked Shri Jitendra Arora, Director (eGovernance) to brief the participants.

3. Director (eGov) briefed the participants that based on the decisions taken in the last meeting held on 26th August, 2015 a sub-committee under the "EHR Review Committee" comprising of Shri B.S. Bedi, Shri S.B. Bhattacharya & Shri Gaur Sunder was entrusted with the task of preparing the revised version of EHR Standards. Thereafter, Director(eGov) requested Shri Bedi to present the same before the Review Committee.

4. Shri B.S. Bedi provided a brief background on the detailed task carried out by the sub-committee related to revision/ updatiton of the standards. Thereafter, he along with Shri Bhattacharya & Shri Gaur Sunder made a presentation highlighting the key revisions proposed in the EHR Standards 2013. The copy of presentation is placed at **Annexure-B.**

5. The sub-committee members, after concluding the presentation, requested that the revised EHR Standards may be reviewed& deliberated upon by the EHR Review Committee and thereafter once approved, the same be notified as updated EHR Standards. They also requested that revisedset of EHR Standards once finalised & approvedmay be forwarded to Bureau of Indian Standards for consideration of adopting those listed standards as Indian Standards as well.

6. Further, Shri Sunil Bhushan, Senior Technical Director, NIC stated that a reference to imaging standards notified by Deity may be incorporated in the document regarding imaging standard being proposed in the revised standards. Dr. Karanvir Singh suggested that different modalities such as mammogram may require slightly higher resolution than the proposed. It was requested that Shri Sunil Bhushan and Dr. Karanvir Singh may accordingly share the details with the Committee so that imaging standards may be set.

7. Shri Amit Mishra, NHSRC requested that the EHR Review Committee may look at national level Public Health Information Systems like Mother & Child Tracking System, Health Management Information System and identify areas where SNOMED-CT can be utilized in an efficient manner. Mr. Gaur Sunder suggested that earlier formed MDDS Committee or NHSRC can study and propose standard compliant (open EHR archetypes) structures, where not already covered in existing archetypes used internationally, that are relevant for capture of clinical data in above mentioned national programs.

195

8. The EHR Review Committee members also discussed & opined that in public health systems, for clinical aspects, EHR standards may be followed and MDDS may address standards for non-clinical aspects if so required and suggested by MDDS committee.The committee members also discussed on the issue of how to address validity of the EHR Standards notified in August 2013 in the context of the revised standards, to be notified after due process.

9. Based on detailed discussions, the following decisions were taken in the meeting:

- The revised EHR Standards document prepared by Sub-committee comprising Shri B.S. Bedi, Shri Bhattacharya & Shri Gaur Sunder may be circulated to all members for their comments, inputs and suggestions.
- eGovernance Division, MoHFW may coordinate with Drug Controller General of India (DCGI) under the gamut of Central Drugs Standard Control Organization (CDSCO) to facilitate building standard compliant drug codes (i.e. encoded list of drugs and required details) for use in EHR as standalone standard or as an India-specific national drug extension of SNOMED CT. Appropriate protocol for building and timely updates may be evolved between the Ministry and DCGI.
- The next meeting of Review Committee should be convened after one month.

The meeting ended with vote of thanks to the chair and the participants.

Annexure – A

List of Participants:

1. Shri Sunil Sharma, JS, MoHFW.... Chairman
2. Shri Jitendra Arora,Director(eGov),MoHFW
3. Shri Sunil Kumar, STD (NIC), MoHFW
4. Shri Gaur Sunder, PTO,C-DAC
5. Dr S B Bhattacharya, Head(Health Informatics), TCS
6. Shri B S Bedi, Adviser,CDAC
7. Prof S N Sarbadhikari, Project Director,CHI of NHP, NIHFW
8. Dr Karanvir Singh, CMIO, Apollo Hospitals
9. Shri Rajesh Narwal, Technical Officer,WHO
10. Shri Balwant Godare, Consultant,WHO Country office
11. Shri Amit Mishra, Sr Consultant, NHSRC, Delhi
12. Syed Quasim Ali, Assistant Director, FICCI
13. Shri Amit Kumar, AD (eGov), MoHFW
14. Shri Chandrasen, PL (ePMU), MoHFW
15. Shri Nikhil Malhotra, Consultant eGov, MoHFW
16. Shri Bhanu Prakash, Consultant eGov, MoHFW

Amit Kumar <amitkumariss34@gmail.com>

Seeking clarification on the decisions taken in the second meeting of EHR Review Committee on 14th December 2015.

Amit Kumar <amitkumariss34@gmail.com> Thu, Dec 31, 2015 at 3:38 PM
To: bedi11@yahoo.com

Sir,

This is in reference to the second meeting of EHR Review Committee on 14th December 2015.

The division need a clarification on the decisions taken in the meeting.(Draft Minutes attached)

The observation of AS(eGov) on the draft minutes is as follows:

Minutes are slightly inconclusive in the sense that what facilitation is required in getting the list of drugs for incorporation in Standards .

Please provide the clarification on the observation of AS(eGov) so that the minutes may be finalised.

Regards

Amit Kumar
Assistant Director (eGovernance)
Ministry of Health & Family Welfare
Room No. 425C
Nirman Bhawan
New Delhi - 110 011
Tel: 011 - 2306 2263
Mobile: 9582861973

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30K

Gmail by Google

Amit Kumar <amitkumariss34@gmail.com>

Seeking clarification on the decisions taken in the second meeting of EHR Review Committee on 14th December 2015.

Baljit Singh Bedi <bsbedi11@gmail.com> Tue, Jan 5, 2016 at 12:46 PM
To: Amit Kumar <amitkumariss34@gmail.com>
Cc: Gaur Sundar <gaurs@cdac.in>, "Dr. S. B. Bhattacharyya" <sbbhattacharyya@gmail.com>

Dear Shri Amit,

Please find attached as desired the revised draft MoM of EHR Review committee meeting held on 14-12-2015 with our suggested line additions/corrections for incorporation.
These have been discussed and finalised in consultations with Shri Gaur Sunder and Dr.S.B.Bhattacharyya,both meembers of the sub-committee.
Please acknowledge.
Best regards
Baljit Bedi
[Quoted text hidden]
--
Baljit Singh Bedi
Adviser,Health Informatics,
Centre for Dev.of Advanced Computing(CDAC),MC&IT,Gov.of India.
&
Member,National EMR Standardisation Committee, MoH&FW,Govt.of India & Chair, Task Group on Interoperabilty;
&
Chair, FICCI India Health Information Network(IHIN) WG on EHR & Standards

Past President,TSI
&
Ex. Sr.Director &Head, Medical Electronics &Telemedicine Div.,DeitY,
MC&IT,Gov.of India

MoM_EHR Standards Review Meeting_14 12 15_V2 0 - Changes_suggested draft.docx
31K

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Department of Health & Family Welfare

e-Governance Division

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Subject: Minutes of the Second Meeting of the Electronic Health Record (EHR) Review Committee held on 14thDecember, 2015

The second meeting of 'EHR Standards Review Committee' was held on 14th December, 2015 at 3:30 P.M. in the Room No.406, A –Wing, NirmanBhawan, Ministry of Health & Family Welfare under the Chairmanship of Shri Sunil Sharma, JS (eGovernance). Representatives from WHO attended the meeting as special invitees. The list of participants is placed at **Annexure - A**.

2. Shri Sunil Sharma, JS(eGov)welcomed the participants and briefed about the overall objective/purpose of EHR Standards which had been notified by MoHFWin August 2013 after detailed deliberations with various stakeholder groups. Hethereafter asked Shri Jitendra Arora, Director (eGovernance) to brief the participants.

3. Director (eGov) briefed the participants that based on the decisions taken in the last meeting held on 26th August, 2015 a sub-committee under the "EHR Review Committee" comprising of Shri B.S. Bedi, Shri Bhattacharya & Shri Gaur Sunder were entrusted with the task of preparing with the revised version of EHR Standards and thereafter requested Shri Bedi to presented the same before the Review Committee.

4. Shri B.S. Bedi provided a brief background on the detailed task carried out by the sub-Committee related to revision/ updationof standards. Thereafter, he along with Shri Bhattacharya & Shri Gaur Sunder made a presentation before the EHR Review Committee highlighting the key changes made in the Revised EHR Standards document in comparison to EHR Standards notified by MoHFW in August 2013. The copy of presentation is placed at **Annexure-B**

5. The sub-committee members, after concluding the presentation, requested that the revised EHR Standards may be reviewed, deliberated upon &adopted by

the EHR Review Committee and thereafter once approved, the samebe notified as National EHR Standards. They also requested that revisedset of EHR Standards be forwarded to Bureau of Indian Standards by MoH&FW, Government of India for consideration of adopting ~~the~~ those listed ~~same~~ standardsas Indian Standards as well.

6. Shri Sunil Bhushan, Senior Technical Director, NIC further stated that a reference to imaging standards notified by Deity may be incorporated in the document in reference to proposed imaging standard in revised set. Dr. Karanvir Singh also suggested that different modalities such as Mammogram may require slightly higher resolution than proposed. It was requested that Shri Sunil Bhushan and Dr. Karanvir Singh may share the details accordingly so that imaging standard may be accordingly set.

7. Shri Amit Mishra, NHSRC also requested that the EHR Review Committee may look at National Level Health Information Systems like Mother & Child Tracking System, Health Information Management System and identify areas where SNOMED-CT can be utilized in an efficient manner. Mr. Gaur Sunder suggested that earlier formed MDDS Committee or NHSRC can study and propose standard compliant (openEHR archeitypes) structures, where not already covered in existing architypes used internationally, that are relevant for capture of clinical data in above mentioned national programs.

8. The EHR Review Committee members also discussed & opined that in public health systems, for clinical aspects, EHR standards ~~may~~ mustbe followed and MDDS may address standards for non-clinical aspects if so required and suggested by MDDS committee.The committee members also discussed on the issue of how to address validity of the EHR standards notified in August 2013 in the context of the revised standards, to be notified after due process.

9. Based on detailed discussions, the following decisions were takenin the meeting:

- The revised EHR Standards document prepared by Sub-committee comprising Shri B.S. Bedi, Shri Bhattacharya & Shri Gaur Sunder should be circulated to all members for their comments, inputs and suggestions.
- Ministrytocoordinate with Drug Controller General of India (DCGI) under the gamut of Central Drugs Standard Control Organization (CDSCO) to facilitatein ~~providing~~ building standard compliant drug codes (encoded list of drugs and required details) for use in EHR as standalone standard or as a India-specific national drug extension of SNOMED CT. Appropriate protocol for building and timely updates may be evolved between the Ministry and D~~GC~~CGI.~~list of drugs for incorporation in the standards.~~
- The Review Committee should meet next after one month.

The meeting ended with vote of thanks to the chair and the participants.

Annexure – A

List of Participants:

1. Shri Sunil Sharma, JS,MoHFW
2. Shri Jitendra Arora,Director(eGov),MoHFW
3. Shri Sunil Kumar,STD (NIC),MoHFW
4. Shri Gaur Sunder,PTO,C-DAC
5. Dr S B Bhattacharya, Head(Health Informatics), TCS~~,Faridabad~~
6. Shri B S Bedi, Adviser,CDAC
7. Prof S N Sarbadhikari,Project Director,CHI of NHP, NIHFW
8. Dr Karanvir Singh, CMIO, Apollo Hospitals
9. Shri Rajesh Narwal, Technical Officer,WHO
10. Shri BalwantGodare,Consultant-,WHO Country office
11. Shri Amit Mishra, Sr Consultant, NHSRC, Delhi
12. Syed Quasim Ali, Assistant Director, FICCI
13. Shri Amit Kumar, AD (eGov),MoHFW
14. Shri Chandrasen, PL (ePMU), MoHFW
15. Shri Nikhil Malhotra, Consultant eGov,MoHFW
16. Shri Bhanu Prakash, Technical Consultant, MoHFW
17. Shri Rahul Vij, Asst Consultant, MoHFW

Draft

180

Department of Health & Family Welfare

e-Governance Division

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Subject: Minutes of the Second Meeting of the Electronic Health Record (EHR) Review Committee held on 14thDecember, 2015

The second meeting of 'EHR Standards Review Committee' was held on 14th December, 2015 at 3:30 P.M. in the Room No.406, A –Wing, Nirman Bhawan, Ministry of Health & Family Welfare under the Chairmanship of Shri Sunil Sharma, JS (eGovernance). Representatives from WHO attended the meeting as special invitees. The list of participants is placed at **Annexure - A**.

2. Shri Sunil Sharma, JS(eGov) welcomed the participants and briefed about the overall objective/purpose of EHR Standards which had been notified by MoHFW in August 2013 after detailed deliberations with various stakeholder groups. He thereafter asked Shri Jitendra Arora, Director (eGovernance) to brief the participants.

3. Director (eGov) briefed the participants that based on the decisions taken in the last meeting held on 26th August, 2015 a sub-committee under the "EHR Review Committee" comprising of Shri B.S. Bedi, Shri Bhattacharya & Shri Gaur Sunder were entrusted with the task of preparing with the revised version of EHR Standards and thereafter requested Shri Bedi to presented the same before the Review Committee.

4. Shri B.S. Bedi provided a brief background on the detailed task carried out by the sub-Committee related to revision/ updation of standards. Thereafter, he along with Shri Bhattacharya & Shri Gaur Sunder made a presentation before the EHR Review Committee highlighting the key changes made in the Revised EHR Standards document in comparison to EHR Standards notified by MoHFW in August 2013. The copy of presentation is placed at **Annexure-B**

5. The sub-committee members, after concluding the presentation, requested that the revised EHR Standards may be reviewed, deliberated upon & adopted by

187

the EHR Review Committee and thereafter once approved, the same be notified as National EHR Standards. They also requested that revised EHR Standards be forwarded to Bureau of Indian Standards by MoH&FW, Government of India for consideration of adopting the same as Indian Standards.

6. Shri Sunil Bhushan, Senior Technical Director, NIC further stated that a reference to imaging standards notified by Deity may be incorporated in the document.

7. Shri Amit Mishra, NHSRC also requested that the EHR Review Committee may look at National Level Health Information Systems like Mother & Child Tracking System, Health Information Management System and identify areas where SNOMED-CT can be utilized in an efficient manner.

8. The EHR Review Committee members also discussed & opined that in public health systems, for clinical aspects, EHR standards may be followed and MDDS may address standards for non-clinical aspects. The committee members also discussed on the issue of how to address validity of the EHR standards notified in August 2013 in the context of the revised standards, to be notified after due process.

9. Based on detailed discussions, the following decisions were taken in the meeting:

- The revised EHR Standards document prepared by Sub-committee comprising Shri B.S. Bedi, Shri Bhattacharya & Shri Gaur Sunder should be circulated to all members for their comments, inputs and suggestions.
- Ministry to facilitate in providing list of drugs for incorporation in the standards.
- The Review Committee should meet next after one month.

The meeting ended with vote of thanks to the chair and the participants.

Annexure – A

List of Participants:

1. Shri Sunil Sharma, JS,MoHFW
2. Shri Jitendra Arora,Director(eGov),MoHFW
3. Shri Sunil Kumar,STD (NIC),MoHFW
4. Shri Gaur Sunder,PTO,C-DAC
5. Dr S B Bhattacharya, Head(Health Informatics), TCS,Faridabad
6. Shri B S Bedi, Adviser,CDAC
7. Prof S N Sarbadhikari,Project Director,CHI of NHP, NIHFW
8. Dr Karanvir Singh, CMIO, Apollo Hospitals
9. Shri Rajesh Narwal, Technical Officer,WHO
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12. Syed Quasim Ali, Assistant Director, FICCI
13. Shri Amit Kumar, AD (eGov), MoHFW
14. Shri Chandrasen, PL (ePMU), MoHFW
15. Shri Nikhil Malhotra, Consultant eGov,MoHFW
16. Shri Bhanu Prakash, Technical Consultant, MoHFW
17. Shri Rahul Vij, ~~Asst~~ Associate Consultant, (TM) MoHFW

EHR Standards
—
Revisions Undertaken

Baljit Singh Bedi
Advisor, CDAC (Sc. Society of MCIT, Govt. of India)
Member, National EMR Standardisation Committee, MoH&FW
& Chair, Sub-Group, Interoperability;
Chair, FICCI EHR Subcommittee
Past President , Telemedicine Society of India(TSI) &
Ex. Sr. Director & Head, Telemedicine Div., Dept. of IT, MCIT, Govt. of India)

Presentation to EHR Revision
Committee-MoHFW-14 Dec 2015

Background - Understanding Information and Communication Technologies (ICTs)

- Healthcare area is highly Data dependent. Power of ICTs lies in its capacity to effectively
- Access data
- Store data
- Analyze data
- Transmit data
- Predictive Analytics

Utilizing this capability of ICTs has the potential to significantly contribute in preventive care, improving delivery , disease control , medical education and training, health management and health research

184

Standardisation- Indian Initiative

- Initiative in suggesting a **Framework for Information Technology Infrastructure for Health(ITIH) in India** (First effort for suggesting a Standard EHR for India)
- National efforts in proposing **Recommendations on Guidelines, Standards & Practices For Telemedicine In India**
- **National Knowledge Commission's India Health Information Network Development (I-HIND)**
- ***EHR Standardization Initiative of MoH&FW***

EMR Standards Committee

- Ministry of Health & Family Welfare (MoH&FW), Govt. of India constituted a Committee of Experts for Development of Standards on EMR in Sept 2010 under Chairmanship of Additional Secretary &DG,CGHS, MoH&FW
- Objective of above Committee to recommend a set of EMR Standards for India to be followed by both public & private healthcare provider
- Procedure for continuous upgradation

Activities Undertaken

- EMR Standardisation Committee set up Sub-Groups related to Standards – Terminology and coding standards, Data connectivity- including H/W,S/W & Interoperability, and Data ownership-Data protection& including security and legal aspects in October 2010
- The EHR standards were a result of the deliberations of the EMR Standards Committee & Subgroups and consolidation by the Sub-committee under FICCI of the public comments on the draft report put up by MoHFW, GoI in their website in May 2013 and deliberations thereof, finalized in August, 2013

Activities Undertaken

- Notified in September, 2013 on MoH&FW Website
- EHR Review Committee formed in August 2015 to review the approved standards and redraft the same with the aim of bringing it in line with current knowledge and understanding
- Incorporate changes, as deemed fit, in view of India becoming a member of IHTSDO in April 2014 and SNOMED CT now being available to all in India

182

Major Revision Points

- Demography data to include person detail and MDDS from DeitY to be used for person details.
- Identifier standards and guidelines added to enable sharing of record across establishments.
- SNOMED CT is clarified as being the primary terminology for all parts of a clinical record, now that India is member country of IHTSDO and SNOMED CT is available to all India entities for free.

Major Revision Points

- LOINC is now recommended for test, measurement and observations. Mapping with SNOMED CT is also mentioned.
- WHO Family of International Classification (that includes ICD, ICF, and few others) is now recommended for classification and reporting.
- Implementation guidelines sections added for each of the standards to help ISVs in implementing them by providing sufficient clarity regarding them.
- Minimum Data Set section has been removed as it is now unnecessary and was in non-conformance with the recommended ISO 13606 standard and archetype based structural composition.

Major Revision Points-contd.

- Security and Privacy standards are indicated with clarity.
- List of supporting and complementing ISO standards streamlined.
- BIS, ISO and other SDOs are now mentioned for selection of standards not provided for specifically.
- HL7 messaging standards have been streamlined to provide greater clarity.

Major Revision Points-contd.

- Scanned document standards have been introduced.
- E-prescription standards have been introduced.
- Device integration standards have been specified.
- Guidelines for hardware/software and data ownership have been revised to provide greater clarity.

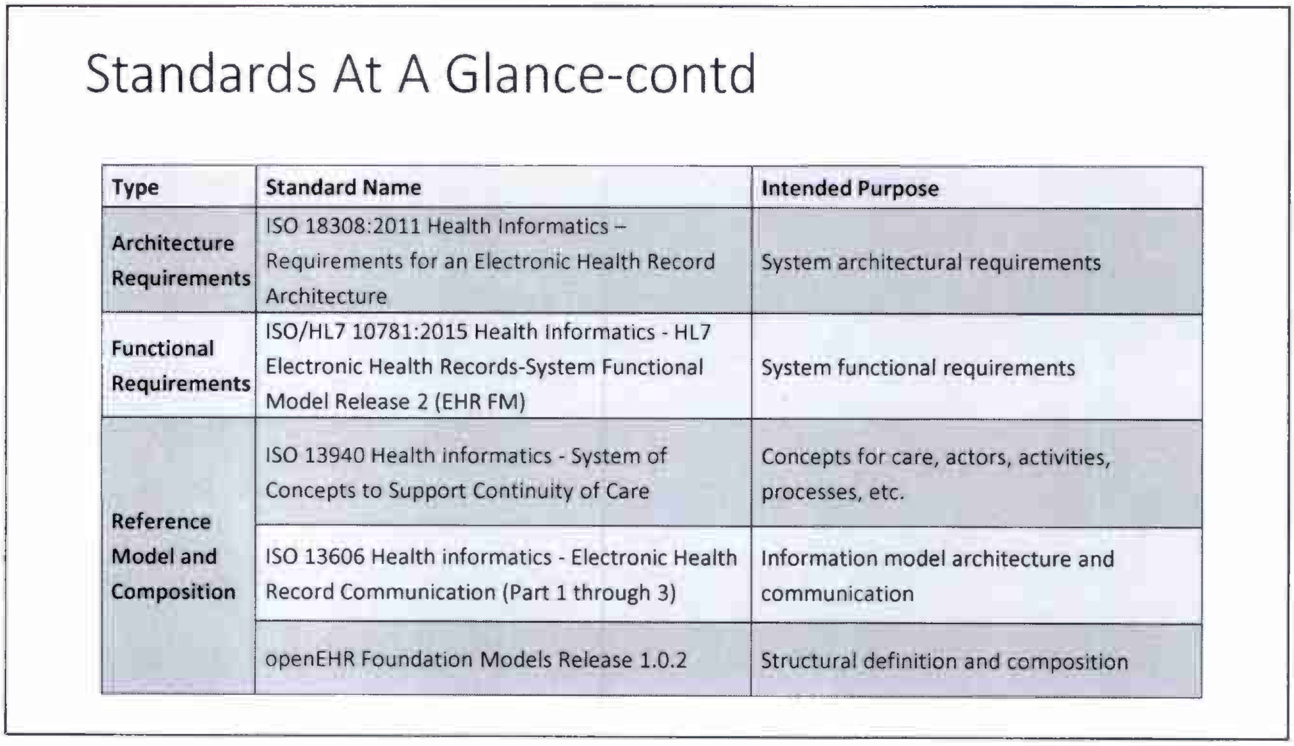
Minor Revision Points

- Standards at a Glance section added to provide tabular list of standards and their intended applicable domain.
- Duplicates removed.
- Glossary streamlined.
- Layout and general document format changed to provide improved readability.

Standards At A Glance

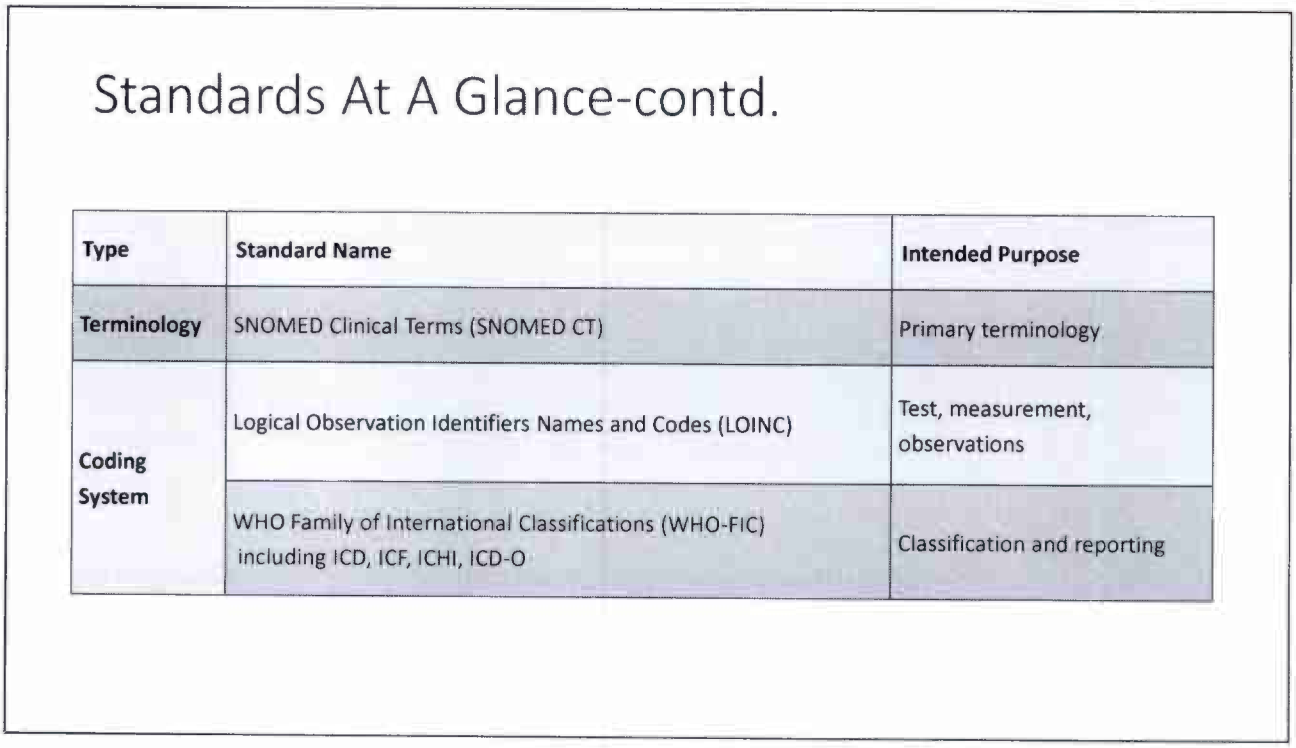
Type	Standard Name	Intended Purpose
Identification & Demographics	ISO/TS 22220:2011 Health Informatics – Identification of Subjects of Health Care	Basic identity details of patient
	MDDS – Demographic (Person Identification and Land Region Codification) version 1.1	Complete demographic for interoperability with E-Governance systems
Patient Identifiers	UIDAI Aadhaar	Preferable identifier where available
	Local Identifier	Identifier given within institution / clinic / lab
	Government Issued Photo Identity Card Number	Identifier in conjunction with local in absence of Aadhaar

22-Dec-15



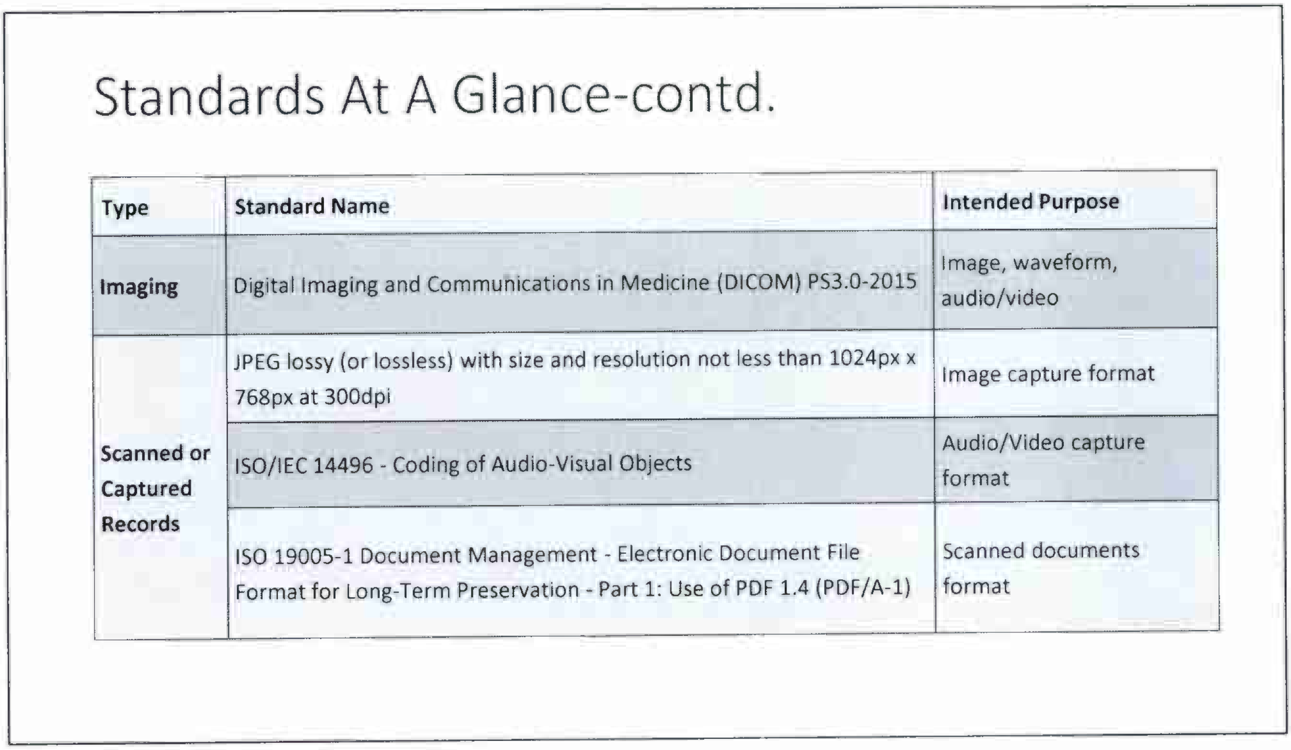
Standards At A Glance-contd

Type	Standard Name	Intended Purpose
Architecture Requirements	ISO 18308:2011 Health Informatics – Requirements for an Electronic Health Record Architecture	System architectural requirements
Functional Requirements	ISO/HL7 10781:2015 Health Informatics - HL7 Electronic Health Records-System Functional Model Release 2 (EHR FM)	System functional requirements
Reference Model and Composition	ISO 13940 Health informatics - System of Concepts to Support Continuity of Care	Concepts for care, actors, activities, processes, etc.
	ISO 13606 Health informatics - Electronic Health Record Communication (Part 1 through 3)	Information model architecture and communication
	openEHR Foundation Models Release 1.0.2	Structural definition and composition



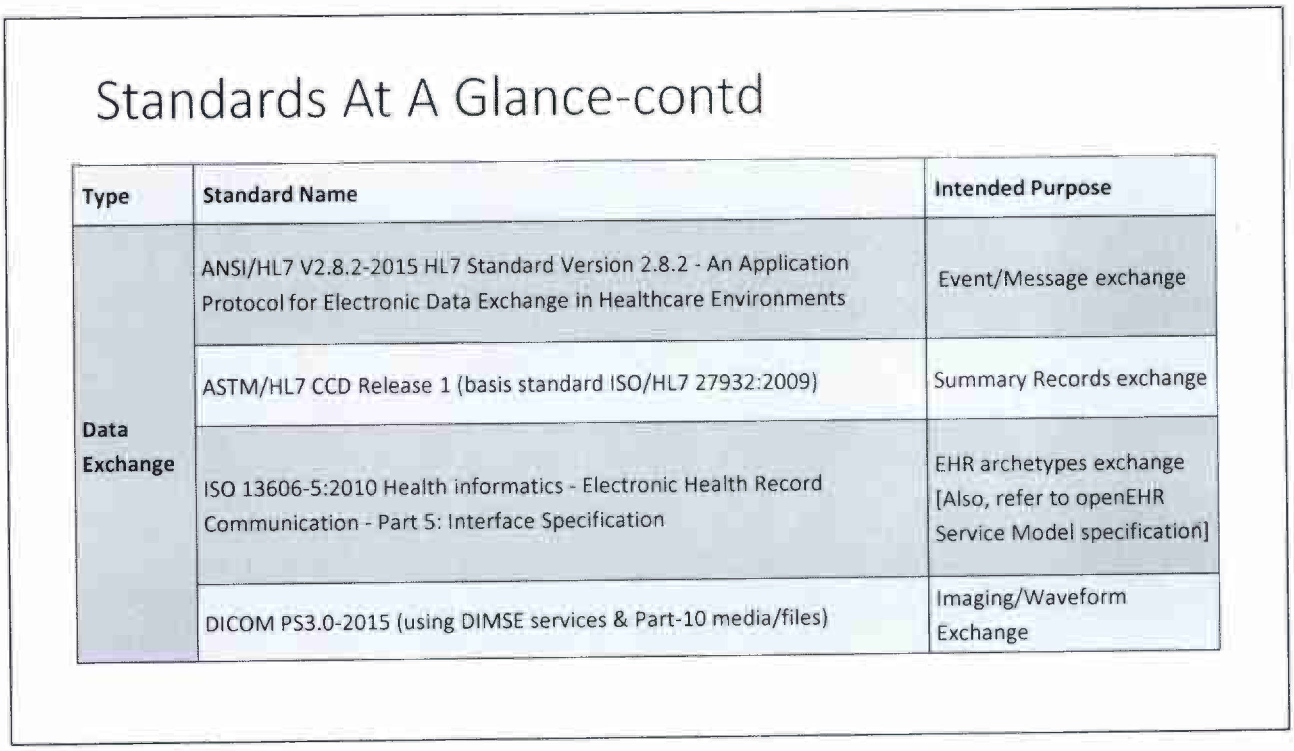
Standards At A Glance-contd.

Type	Standard Name	Intended Purpose
Terminology	SNOMED Clinical Terms (SNOMED CT)	Primary terminology
Coding System	Logical Observation Identifiers Names and Codes (LOINC)	Test, measurement, observations
	WHO Family of International Classifications (WHO-FIC) including ICD, ICF, ICHI, ICD-O	Classification and reporting



Standards At A Glance-contd.

Type	Standard Name	Intended Purpose
Imaging	Digital Imaging and Communications in Medicine (DICOM) PS3.0-2015	Image, waveform, audio/video
Scanned or Captured Records	JPEG lossy (or lossless) with size and resolution not less than 1024px x 768px at 300dpi	Image capture format
	ISO/IEC 14496 - Coding of Audio-Visual Objects	Audio/Video capture format
	ISO 19005-1 Document Management - Electronic Document File Format for Long-Term Preservation - Part 1: Use of PDF 1.4 (PDF/A-1)	Scanned documents format



Standards At A Glance-contd

Type	Standard Name	Intended Purpose
Data Exchange	ANSI/HL7 V2.8.2-2015 HL7 Standard Version 2.8.2 - An Application Protocol for Electronic Data Exchange in Healthcare Environments	Event/Message exchange
	ASTM/HL7 CCD Release 1 (basis standard ISO/HL7 27932:2009)	Summary Records exchange
	ISO 13606-5:2010 Health informatics - Electronic Health Record Communication - Part 5: Interface Specification	EHR archetypes exchange [Also, refer to openEHR Service Model specification]
	DICOM PS3.0-2015 (using DIMSE services & Part-10 media/files)	Imaging/Waveform Exchange

22-Dec-15

Standards At A Glance-contd.

Type	Standard Name	Intended Purpose
Other Relevant Standards	Bureau of Indian Standards and its MHD-17 Committee ISO TC 215 set of standards IEEE/NEMA/CE standards for physical systems and interfaces	Standards Development Organizations (SDOs)
Discharge/ Treatment Summary	Medical Council of India (MCI) under regulation 3.1 of Ethics	Composition as prescribed
E-Prescription	Pharmacy Practice Regulations, 2015 Notification No. 14-148/ 2012- PCI as specified by Pharmacy Council of India	Composition as prescribed
Personal Healthcare and medical Device Interface	IEEE 11073 health informatics standards and related ISO standards for medical devices	Device interfacing

Standards At A Glance-contd

Type	Standard Name	Intended Purpose
Data Privacy and Security	ISO/TS 14441:2013 Health Informatics – Security & Privacy Requirements of EHR Systems for Use in Conformity Assessment	Basis security and privacy requirements
Information Security Management	ISO/DIS 27799 Health informatics - Information Security Management in Health using ISO/IEC 27002	Overall information security management
Privilege Management and Access Control	ISO 22600:2014 Health informatics - Privilege Management and Access Control (Part 1 through 3)	Access control
Audit Trail and Logs	ISO 27789:2013 Health informatics - Audit trails for Electronic Health Records	Audit trail
Data Integrity	Secure Hash Algorithm (SHA) used must be SHA-256 or higher	Data Hashing

Standards At A Glance-contd.

Type	Standard Name	Intended Purpose
Data Encryption	Minimum 256-bits key length	Encryption key
	HTTPS, SSL v3.0, and TLS v1.2	Encrypted connection
Digital Certificate	ISO 17090 Health informatics - Public Key Infrastructure (Part 1 through 5)	Digital certificates use and management

Supporting / Complementing Standards

Standard	Description
ISO 12967:2009	Health Informatics - Service Architecture (Parts 1 - 3)
ISO 13972:2015	Health Informatics - Detailed Clinical Models, Characteristics and Processes
ISO 20301:2014	Health Informatics - Health Cards - General Characteristics
ISO 21090:2011	Health Informatics - Harmonized Data Types for Information Interchange
ISO 8601:2004	Data elements and Interchange Formats - Information Interchange - Representation of Dates and Times
ISO 13119:2012	Health Informatics - Clinical Knowledge Resources - Metadata
ISO 22857:2013	Health Informatics – Guidelines on Data Protection to Facilitate Trans-Border Flows of Personal Health Data
ISO 21549-1:2013	Health Informatics — Patient Healthcard Data — Part 1: General Structure
ISO TS 14265:2011	Classification of Purposes for Processing Personal Health Information
ISO TS 27527:2010	Health Informatics – Provider Identification

New Additions

- SNOMED CT to be the primary terminology code system for all parts of a clinical record
- LOINC and ICD is to be used as per requirement like reporting, epidemiological analysis, etc.
- Standards for scanned documents have been introduced
- Duplications and conflicts resolved, namely
  - Minimum Data Set section has been removed as it conflicted with ISO 13606 requirements
- BIS-mandated ISO standards have been incorporated

Recommendations (to the committee)

- The revised EHR Standards be adopted and approved after deliberation as National EHR Standards
- These EHR Standards be forwarded to Bureau of Indian Standards by MoH&FW, Government of India for consideration of adopting the same as Indian Standards

22-Dec-15

Thank you

bedi11@yahoo.com

Ministry of Health & Family Welfare
e-Governance Division

****

Subject: Second meeting of EHR Review Committee.
Venue: 406-A Wing. Time: 03.30 PM. Date: 14th December, 2015.

S. No.	Name	Designation	Official Address	e-mail ids	Mobile Number	Sign.
1.	RAHUL VIJ	ASS. CONSULTANT	EITA	RAHUL.VIJ@GOV.IN	9718100842	Rahul Vij
2.	Bhanu Prakash	Consultant	Deloitte Consulting Services	bhanuprakash@deloitte.com	9811576222	
3. 9	Rajesh Narwal	Technical officer	WHO	narwalr@who.int	9871968672	
4. 12	Syed Quasim Ali	Assistant Director	FICCI	quasim.ali@ficci.com	9560989534	Syed Quasim Ali
5. 2	JITENDRA ARORA	Director (eGov)	MoHFW	dir.ehealth@gmail.com	9868453680	J Arora
6. 1	SUNIL SHARMA	JS	MoHFW	sunil.sharma62@gov.in	9717644079	
7. 4	Gaur Sunder	Principal Tech officer	C-DAC	gaurs@cdac.in	9422512661	
8. 5	Dr SB Bhattacharya	Head, Health Informatics, TCS	776/Sector 15, Faridabad	sbbhattacharya2@gmail.com	9810595261	

S. No.	Name	Designation	Official Address	e-mail ids	Mobile Number	Sign.
9. 6	B.S. BEDI	Adviser	CDAC	bsbedi11@gmail.com	9868243335	
10. 3	SUNIL KUMAR	Senior Technical Director	NIC	Sunil.bhushan@nic.in	9810901302	
11. 7	Prof. S.N. SARBADHIKARI	Project Director	CHI & NHP, NIHFW	SUPTEN@GMAIL.COM	9717669574	
12. 8	Dr Karanvir Singh	CMIO	Apollo Hospital	Karanvir.singh@gmail.com	9810090988	
13. 19	Dr AMIT MISHRA	Sr. Consultant	NHSRC, Delhi	dr.amitmishra@gmail.com	9910011595	
14. 10	Balwant Godara	Consultant	WHO country office	godarab@who.int	9787809438	
15.						
16.						
17.						
18.						
19.						

Subject: **Fwd: Meeting of EHR Review Committee on 14th December, 2015 at 3.30 PM in Nirman Bhawan, New Delhi.**
To: shobha.mishra@ficci.com, narwalr@who.int, dr.amitmishra@gmail.com
Cc: Jitendra Arora <dir.ehealth@gmail.com>
Date: 12/09/15 04:40 PM
From: "Amit Kumar" <amit.k89@gov.in>

Meeting Notice

Subject: Meeting of EHR Review Committee on 14th December, 2015 at 3.30 PM in Nirman Bhawan, New Delhi.

Ministry of Health and Family Welfare notified Electronic Health Record (EHR) Standards in September 2013 to encourage standardization, integration and electronic information exchange amongst the various healthcare providers.

2. EHR Review Committee has been constituted in MoHFW with the approval of Secretary (HFW) to review the aforementioned standards.

3. The second meeting of the EHR Review Committee under the Chairmanship of Shri Sunil Sharma, JS (eGov) has now been re- scheduled for **3.30 PM on 14th December, 2015** in Room No 406-A wing, Nirman Bhawan, New Delhi.

4. You are requested to kindly take part in the meeting as a 'Special Invitee' as per the above schedule.

To,

Ms Shobha Mishra Ghosh, Senior Director, FICCI

Dr Rajesh Narwal, Technical Director, Health System Regulations, WHO

Mr Amit Mishra, Senior Consultant, NHSRC

-------- Original Message --------
From: **Jitendra Arora** <dir.ehealth@gmail.com>
Date: Dec 8, 2015 6:03:10 PM
Subject: Meeting of EHR Review Committee on 14th December, 2015 at 3.30 PM in Nirman Bhawan, New Delhi.
To: "Prof. Supten Sarbadhikari" <supten@gmail.com>, "Dr. S. B. Bhattacharyya" <sbbhattacharyya@gmail.com>, kbhatia@gov.in, Gaur Sunder <gaurs@cdac.in>, "Dr. B.S. Bedi" <bedi11@yahoo.com>, Sunil Kumar <sunil.bhushan@gov.in>, drkaranvir_s@apollohospitals.com, sunil.sharma62@gov.in
Cc: "Shrivastava, Chandrasen (IN - Delhi)" <chandrasens@deloitte.com>, "Prakash, Bhanu (IN - Delhi)" <bhanuprakash@deloitte.com>, Agarwal K B AS <asfnd.kb@gmail.com>, Sunita Dhaundiyal <sunita.dhaundiyal@nic.in>, Nikhil Malhotra <nimalhotra@deloitte.com>, ANKIT TRIPATHI <ankit_tripathi11@hotmail.com>, Amit Kumar <amit.k89@gov.in>

Meeting Notice

Subject: Meeting of EHR Review Committee on 14th December, 2015 at 3.30 PM in Nirman Bhawan, New Delhi.

Ministry of Health and Family Welfare notified Electronic Health Record (EHR) Standards in September 2013 to encourage standardization, integration and electronic information exchange amongst the various healthcare providers.

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4. All the addressees are requested to kindly make it convenient to attend the meeting as per the above schedule.

To:

1. Dr Supten Sarbadhikari, Project Director (NHP), NIHFW
2. Ms. Kavita Bhatia, Scientist 'E', DeitY
3. Shri Jitendra Arora, Director (eGov), MoHFW
4. Dr. S B Bhattacharya, Head Health Informatics, TCS
5. Dr B.S. Bedi, Advisor, CDAC, Delhi
6. Shri. Gaur Sunder, CDAC, Pune
7. Shri. Sunil Kumar Bhushan, NIC, Health
8. Dr. Karanvir Singh, CIO, Apollo Hospitals
9. PL (ePMU team), MoHFW

Copy to:

1. PPS to AS (KBA), MoHFW
2. PPS to JS (eGov), MoHFW

Regards

Jitendra Arora
Director(eHealth)
Ministry of Health and Family Welfare
Nirman Bhawan (Room 307D)
New Delhi - 110108.
+91-11-23062317 (Telefax).
+91-9868453680(Mobile)

--

Subject: **Re: Meeting of Committee to review comments received on the Concept note of NeHA.**
Date: 12/08/15 05:42 PM
From: Jitendra Arora <dir.ehealth@gmail.com>
To: "NARWAL, Rajesh" <narwalr@who.int>,
"supten@gmail.com" <supten@gmail.com>,
"bedi11@yahoo.com" <bedi11@yahoo.com>,
"ramkicdac@gmail.com" <ramkicdac@gmail.com>,
Vinay Thakur <vinay@gov.in>, "gaurs@cdac.in" <gaurs@cdac.in>
Cc: Amit Kumar <amit.k89@gov.in>,
"ankit_tripathi11@hotmail.com" <ankit_tripathi11@hotmail.com>,
"sunil.sharma62@gov.in" <sunil.sharma62@gov.in>,
"chandrasens@deloitte.com" <chandrasens@deloitte.com>,
"nimalhotra@deloitte.com" <nimalhotra@deloitte.com>

Meeting Notice / बैठकनोटिस

Subject: Meeting of Committee to review comments received on the Concept note of NeHA.

The first meeting of the Committee to review comments received on the Concept note of NeHA has been re- scheduled to be held under the chairmanship of Prof. S.N. Sarbadhikari on 14th December, 2015 at 11:00 AM in Room No. 406-A wing, Nirman Bhawan, New Delhi followed by Lunch.

2. All the addressees are requested to kindly make it convenient to attend the meeting as per the above schedule.

To:

1) Prof. S N Sarbadhikari, NIHFW

2) Shri S Ramki, Advisor, NISG

3) Shri B S Bedi, Advisor, C-DAC

4) Shri Gaur Sunder, C-DAC Pune iNRC SNOMED CT India

5) Shri Vinay Thakur, Director (eGov), DeitY

6) Shri Rajesh Narwal, Representative, WHO

Regards

Jitendra Arora
Director(eHealth)
Ministry of Health and Family Welfare
Nirman Bhawan (Room 307D)
New Delhi - 110108.
+91-11-23062317 (Telefax),
+91-9868453680(Mobile)

On Sat, Dec 5, 2015 at 8:32 PM, Jitendra Arora <dir.ehealth@gmail.com> wrote:

> Dear Sir,

Subject: **Meeting of EHR Review Committee on 14th December, 2015 at 3.30 PM in Nirman Bhawan, New Delhi.**
Date: 12/08/15 06:03 PM
From: Jitendra Arora <dir.ehealth@gmail.com>
To: "Prof. Supten Sarbadhikari" <supten@gmail.com>,
"Dr. S. B. Bhattacharyya" <sbbhattacharyya@gmail.com>,
kbhatia@gov.in, Gaur Sunder <gaurs@cdac.in>,
"Dr. B.S. Bedi" <bedi11@yahoo.com>,
Sunil Kumar <sunil.bhushan@gov.in>,
drkaranvir_s@apollohospitals.com, sunil.sharma62@gov.in
Cc: "Shrivastava, Chandrasen (IN - Delhi)" <chandrasens@deloitte.com
"Prakash, Bhanu (IN - Delhi)" <bhanuprakash@deloitte.com>,
Agarwal K B AS <asfnd.kb@gmail.com>,
Sunita Dhaundiyal <sunita.dhaundiyal@nic.in>,
Nikhil Malhotra <nimalhotra@deloitte.com>,
ANKIT TRIPATHI <ankit_tripathi11@hotmail.com>,
Amit Kumar <amit.k89@gov.in>

Meeting Notice

Subject: **Meeting of EHR Review Committee on 14th December, 2015 at 3.30 PM in Nirman Bhawan, New Delhi.**

Ministry of Health and Family Welfare notified Electronic Health Record (EHR) Standards in September 2013 to encourage standardization, integration and electronic information exchange amongst the various healthcare providers.

2. EHR Review Committee has been constituted in MoHFW with the approval of Secretary (HFW) to review the aforementioned standards.

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4. All the addressees are requested to kindly make it convenient to attend the meeting as per the above schedule.

To:

1. Dr Supten Sarbadhikari, Project Director (NHP), NIHFW
2. Ms. Kavita Bhatia, Scientist 'E', DeitY
3. Shri Jitendra Arora, Director (eGov), MoHFW
4. Dr. S B Bhattacharya, Head Health Informatics, TCS
5. Dr B.S. Bedi, Advisor, CDAC, Delhi
6. Shri. Gaur Sunder, CDAC, Pune
7. Shri. Sunil Kumar Bhushan, NIC, Health

8. Dr. Karanvir Singh, CIO, Apollo Hospitals

9. PL (ePMU team), MoHFW

Copy to:

1. PPS to AS (KBA), MoHFW

2. PPS to JS (eGov), MoHFW

Regards

Jitendra Arora
Director(eHealth)
Ministry of Health and Family Welfare
Nirman Bhawan (Room 307D)
New Delhi - 110108.
+91-11-23062317 (Telefax),
+91-9868453680(Mobile)

Subject: **Notable changes in the revised EHR Standards document**
To: Agarwal K B AS <asfnd.kb@gmail.com>, sunil.sharma62@gov.in
Cc: K L Sharma JS <kl.sharma58@nic.in>,
Jitendra Arora <dir.ehealth@gmail.com>,
Sunita Dhaundiyal <sunita.dhaundiyal@nic.in>,
"amit.k89@gov.in" <amit.k89@gov.in>,
"Nikhil R (IN - Delhi)" <nimalhotra@deloitte.com>,
Gaur Sundar <gaurs@cdac.in>,
"Dr. S. B. Bhattacharyya" <sbbhattacharyya@gmail.com>

Date: 11/30/15 02:12 PM
From: Baljit Singh Bedi <bsbedi11@gmail.com>

Notable Changes in November 2015 revision of EHR S... (16kB)

Dear Sir,

This is reference to the revised EHR Standards document sent earlier and request for a brief comparison highlighting the changes/revisions made in the revised draft EHR Standards document w.r.t. the EHR Standards notified by MoHFW in September, 2013.

Please find attached a document that lists out the revisions in brief as mentioned above.

I will also highlight these during my presentation to the EHR Revision Committee on 2nd December 2015 at MoH&FW.

--
Baljit Singh Bedi
Adviser,Health Informatics,
Centre for Dev.of Advanced Computing(CDAC),MC&IT,Gov.of India.
&
Member,National EMR Standardisation Committee, MoH&FW,Govt.of India & Chair, Task Group on Interoperabilty;
&
Chair, FICCI India Health Information Network(IHIN) WG on EHR & Standards

Past President,TSI
&
Ex. Sr.Director &Head, Medical Electronics &Telemedicine Div.,DeitY,
MC&IT,Gov.of India

Notable Changes in November 2015 Revision of EHR Standards for India

Major

1. Demography data to include person detail and MDDS from DeitY to be used for person details.
2. Identifier standards and guidelines added to enable sharing of record across establishments.
3. SNOMED CT usage expanded to act as the primary terminology for all clinical data, now that India is member country of IHTSDO and SNOMED CT is available to all India entities for free.
4. LOINC is now recommended for test, measurement and observations. Mapping with SNOMED CT is also mentioned.
5. WHO Family of International Classification (that includes ICD, ICF, and few others) is now recommended for classification and reporting.
6. Implementation guidelines sections added for each of the standards to help ISVs in implementing them by providing sufficient clarity regarding them.
7. Minimum Data Set section has been removed as it is now unnecessary and was in non-conformance with the recommended ISO 13606 standard and archetype based structural composition.
8. Security and Privacy standards are indicated with clarity.
9. List of supporting and complementing ISO standards streamlined.
10. BIS, ISO and other SDOs are now mentioned for selection of standards not provided for specifically.
11. HL7 messaging standards have been streamlined to provide greater clarity.
12. Scanned document standards have been introduced.
13. E-prescription standards have been introduced.
14. Device integration standards have been specified.
15. Guidelines for hardware/software and data ownership have been revised to provide greater clarity.

Minor

1. Standards at a Glance section added to provide tabular list of standards and their intended applicable domain.
2. Duplicates removed.
3. Glossary streamlined.
4. Layout and general document format changed to provide improved readability.

Subject: **RE: Meeting of EHR Review Committee on 02th December, 2015 at 11.30 AM in Nirman Bhawan, New Delhi.**
Date: 11/24/15 11:26 AM
From: "NARWAL, Rajesh" <narwalr@who.int>
To: "amit.k89@gov.in" <amit.k89@gov.in>,
"Sanjiv.mital@nisg.org" <Sanjiv.mital@nisg.org>,
"shobha.mishra@ficci.com" <shobha.mishra@ficci.com>,
"dr.amitmishra@gmail.com" <dr.amitmishra@gmail.com>
Cc: "asfnd.kb@gmail.com" <asfnd.kb@gmail.com>,
Sunil Sharma JS <sunil.sharma62@gov.in>,
Sunita Dhaundiyal <sunita.dhaundiyal@nic.in>,
"chandrasens@deloitte.com" <chandrasens@deloitte.com>,
"nimalhotra@deloitte.com" <nimalhotra@deloitte.com>,
"bhanuprakash@deloitte.com" <bhanuprakash@deloitte.com>,
"bedi11@yahoo.com" <bedi11@yahoo.com>

image003.jpg (3kB)

Dear Mr Amit Kumar,

Thank you for the invite and I would have surely wished to attend but due to the prescheduled 'Joint Monitoring Mission of the IDSP' during the same period- it will miss this important meeting. On a separate note, I would like to reiterate few broad tenets for the consideration of the Expert Group;

- As a first step it may be useful to align the strategy for review/ updation of the EHR standards to the current health policy context e.g.: What is the right mix of different standards that may be considered for India- SNOMED CT, ICD-10, Loink, NANDA…? What are the pros and cons of having more/less standards? What could be the periodicity and institutional mechanisms for future reviews?
- Given the heterogeneous and huge healthcare sector in India EHR standards may be kept simple and intuitive enough to be adopted by smaller hospitals and clinics also, rather than solely tailored to the capabilities of Tertiary Care or Corporate hospitals. Infact, different levels of complexity can be inbuilt so that end users could choose specific levels of EHR they wish to use according to their needs and proficiency (may not be in totality)

WHO would be very happy to contribute further, as deemed necessary by the MoHFW/ EHR Expert Committee

Thanks and regards
Rajesh

Dr Rajesh Narwal, MD, MPH
Technical Officer- Health Systems Stewardship and Regulations
World Health Organization
Country Office- India
Phone: +91 11 66564800, GPN: 23232
Fax: +91 11 26162996
Mob (off.): +91 9871968672
Web: http://www.searo.who.int/india/en/

*No 'Universal Health Coverage' without **effective Stewardship** (Policy Guidance/ Health System Design/ Collaboration & Partnerships/ Health intelligence & Oversight/ Regulation/ Accountability)*

164

From: amit.k89@gov.in [mailto:amit.k89@gov.in]
Sent: 20 November 2015 17:41
To: Sanjiv.mital@nisg.org; shobha.mishra@ficci.com; NARWAL, Rajesh; dr.amitmishra@gmail.com
Cc: asfnd.kb@gmail.com; Sunil Sharma JS; Sunita Dhaundiyal; chandrasens@deloitte.com; nimalhotra@deloitte.com; bhanuprakash@deloitte.com
Subject: Meeting of EHR Review Committee on 02th December, 2015 at 11.30 AM in Nirman Bhawan, New Delhi.

Meeting Notice

Meeting of EHR Review Committee on 2nd December, 2015 at 11.30 AM in Nirman Bhawan, New Delhi.

Ministry of Health and Family Welfare notified Electronic Health Record (EHR) Standards in September 2013 to encourage standardization, integration and electronic information exchange amongst the various healthcare providers.

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3. You are requested to kindly take part in the meeting as a 'Special Invitee' as per the above schedule.

To:

Mr Sanjiv Mital, CEO, NISG

Ms Shobha Mishra Ghosh, Senior Director, FICCI

Dr Rajesh Narwal, Technical Director, Health System Regulations, WHO

Mr Amit Mishra, Senior Consultant, NHSRC

Copy to:

PPS to AS (KBA), MoHFW

PPS to JS (eGov), MoHFW

Regards
Amit Kumar
Assistant Director (eGovernance)
Ministry of Health & Family Welfare
Room No. 425C
Nirman Bhawan
New Delhi – 110 011
Tel: 011 – 2306 2263
Mobile: 9582861973

Subject: **Meeting of EHR Review Committee on 2nd December, 2015 at 11.30 AM in Nirman Bhawan, New Delhi.**
Date: 11/20/15 06:00 PM
From: "Amit Kumar" <amit.k89@gov.in>
To: supten@nihfw.org, supten@gmail.com,
ankit_tripathi11@hotmail.com, kbhatia@gov.in,
sbbhattacharyya@gmail.com, gaurs@cdac.in, bedi11@yahoo.com,
"Sunil Kumar" <sunil.bhushan@gov.in>,
drkaranvir_s@apollohospitals.com,
"Jitendra Arora" <dir.ehealth@gmail.com>,
chandrasens@deloitte.com, nimalhotra@deloitte.com,
bhanuprakash@deloitte.com
Cc: asfnd.kb@gmail.com, sunil.sharma62@gov.in,
Sunita Dhaundiyal <sunita.dhaundiyal@nic.in>

Meeting notice - EHR review committee 02.12.2015.p... (402kB)

Meeting Notice

Meeting of EHR Review Committee on 2nd December, 2015 at 11.30 AM in Nirman Bhawan, New Delhi.

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To:

Dr Supten Sarbadhikari, Project Director (NHP), NIHFW

Ms. Kavita Bhatia, Scientist 'E', DeitY

Shri Jitendra Arora, Director (eGov), MoHFW

Dr. S B Bhattacharya, Head Health Informatics, TCS

Dr B.S. Bedi, Advisor, CDAC, Delhi

Shri. Gaur Sunder, CDAC, Pune

Shri. Sunil Kumar Bhushan, NIC, Health

Dr. Karanvir Singh, CIO, Apollo Hospitals

PL (ePMU team), MoHFW

Copy to:

PPS to AS (KBA), MoHFW

PPS to JS (eGov), MoHFW

Regards
Amit Kumar
Assistant Director (eGovernance)
Ministry of Health & Family Welfare
Room No. 425C
Nirman Bhawan
New Delhi – 110 011
Tel: 011 – 2306 2263
Mobile: 9582861973

161

F. No. Q-11013/3/2015-eGov
Government of India / भारत सरकार
D/o Health and Family Welfare/ स्वास्थ्य एवं परिवार कल्याण विभाग
e-Governance Section /(ई-गवर्नेंस अनुभाग)

*****

निर्माण भवन, नई दिल्ली
दिनांक: 20 नवम्बर 2015

Meeting Notice / बैठक नोटिस

Subject: **Meeting of EHR Review Committee on 2nd December, 2015 at 11.30 AM in Nirman Bhawan, New Delhi.**

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3. All the addressees are requested to kindly make it convenient to attend the meeting as per the above schedule.

सुनीता ढौंडियाल
(सुनीता ढौंडियाल)
अवर सचिव (ई-गवर्नेंस)
फोन : 23061843

To:

1. Dr Supten Sarbadhikari, Project Director (NHP), NIHFW
2. Ms. Kavita Bhatia, Scientist 'E', DeitY
3. Shri Jitendra Arora, Director (eGov), MoHFW
4. Dr. S B Bhattacharya, Head Health Informatics, TCS
5. Dr B.S. Bedi, Advisor, CDAC, Delhi
6. Shri. Gaur Sunder, CDAC, Pune
7. Shri. Sunil Kumar Bhushan, NIC, Health
8. Dr. Karanvir Singh, CIO, Apollo Hospitals
9. PL (ePMU team), MoHFW

Copy to:

1. PPS to AS (KBA), MoHFW
2. PPS to JS (eGov), MoHFW

160

Subject: **Meeting of EHR Review Committee on 02th December, 2015 at 11.30 AM in Nirman Bhawan, New Delhi.**
To: Sanjiv.mital@nisg.org, shobha.mishra@ficci.com, narwalr@who.int, dr.amitmishra@gmail.com
Cc: asfnd.kb@gmail.com, Sunil Sharma JS <sunil.sharma62@gov.in>, Sunita Dhaundiyal <sunita.dhaundiyal@nic.in>, chandrasens@deloitte.com, nimalhotra@deloitte.com, bhanuprakash@deloitte.com

Date: 11/20/15 05:40 PM
From: "Amit Kumar" <amit.k89@gov.in>

Meeting Notice

Meeting of EHR Review Committee on 2nd December, 2015 at 11.30 AM in Nirman Bhawan, New Delhi.

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3. You are requested to kindly take part in the meeting as a 'Special Invitee' as per the above schedule.

To:

Mr Sanjiv Mital, CEO, NISG

Ms Shobha Mishra Ghosh, Senior Director, FICCI

Dr Rajesh Narwal, Technical Director, Health System Regulations, WHO

Mr Amit Mishra, Senior Consultant, NHSRC

Copy to:

PPS to AS (KBA), MoHFW

PPS to JS (eGov), MoHFW

Regards
Amit Kumar
Assistant Director (e-Governance)
Ministry of Health and Family Welfare
Room No. [illegible]
Nirman Bhawan
New Delhi – [illegible]
Tel: 011 – 2306 [illegible]
Mobile: 95[illegible]

F. No. Q-11013/3/2015-eGov
Government of India / भारत सरकार
D/o Health and Family Welfare/ स्वास्थ्य एवं परिवार कल्याण विभाग
e-Governance Section /(ई-गवर्नेंस अनुभाग)
*****

निर्माण भवन, नई दिल्ली

दिनांक: 20 नवम्बर 2015

Meeting Notice / बैठक नोटिस

Subject: **Meeting of EHR Review Committee on 2nd December, 2015 at 11.30 AM in Nirman Bhawan, New Delhi.**

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सुनीता ढौंडियाल

(सुनीता ढौंडियाल)
अवर सचिव (ई-गवर्नेंस)
फोन : 23061843

To:

1. Mr Sanjiv Mital, CEO, NISG
2. Ms Shobha Mishra Ghosh, Senior Director, FICCI
3. Dr Rajesh Narwal, Technical Director, Health System Regulations, WHO
4. Mr Amit Mishra, Senior Consultant, NHSRC

Copy to:

1. PPS to AS (KBA), MoHFW
2. PPS to JS (eGov), MoHFW

Amit Kumar <amitkumariss34@gmail.com>

Fwd: Draft revised EHR Standards

1 message

Sunita Dhaundiyal <sunitadhaundiyal@gmail.com> Tue, Nov 10, 2015 at 2:09 PM
To: Amit Kumar <amitkumariss34@gmail.com>

---------- Forwarded message ----------
From: **Jitendra Arora** <dir.ehealth@gmail.com>
Date: Tue, Nov 10, 2015 at 1:05 PM
Subject: Fwd: Draft revised EHR Standards
To: "Shrivastava, Chandrasen (IN - Delhi)" <chandrasens@deloitte.com>, Sunita Dhaundiyal <Sunitadhaundiyal@gmail.com>, Nikhil Malhotra <nimalhotra@deloitte.com>

Regards

Jitendra Arora
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---------- Forwarded message ----------
From: **Baljit Singh Bedi** <bsbedi11@gmail.com>
Date: Thu, Nov 5, 2015 at 3:58 PM
Subject: Draft revised EHR Standards
To: Agarwal K B AS <asfnd.kb@gmail.com>
Cc: sunil.sharma62@gov.in, K L Sharma JS <kl.sharma58@nic.in>, Jitendra Arora <dir.ehealth@gmail.com>, Gaur Sundar <gaurs@cdac.in>, "Dr. S. B. Bhattacharyya" <sbbhattacharyya@gmail.com>

Sir,
It is my pleasure to attach on behalf of the Sub-committee of Electronic Health Record (EHR) review committee set up under your Chairmanship, the Draft of finalised "ELECTRONIC HEALTH RECORD (EHR) STANDARDS FOR INDIA" for cosideration of the Review Committee.
The Report is result of intense exercise carried out by members of the Sub-committee over more than two months. I shall like to put on record the contribution of Shri Gaur Sunder,CDAC Pune and Dr. S.B. Bhattacharyya, TCS,other two Members, in this challenging exercise.
Both with in depth domain expertise in overall understanding of EHR Standards including SNOMED-CT and current international scenario, are the key contributors in this effort.
Effort includes the updation taken place internationally in the ealier notified standards,MDDS incorporation in relevant sections,part revsion/correction of the earlier text ,and other issues in the updated document.
I would also like to meet you and other senior officers of MoH&FW to present High lights of the effort.
I have attached a pdf version also,in case you would like to circulate it to othar members of the Review committee.

Warm regards
Sincerely,
Baljit Bedi
--
Baljit Singh Bedi
Coordinator, Revision EHR Draft Committee, MoH & FW
&
Adviser,Health Informatics,
Centre for Dev.of Advanced Computing(CDAC),MC&IT,Gov.of India.
&
Member,National EHR Standardisation Committee, MoH&FW,Govt.of India &
Chair, Task Group on Interoperabilty;
&
Chair, FICCI India Health Information Network(IHIN) WG on EHR & Standards

Past President,TSI
&
Ex. Sr.Director &Head, Medical Electronics &Telemedicine Div.,DeitY,
MC&IT,Gov.of India

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2 attachments

EHR Standards for India - 2015 - Final Draft - 4 November 2015[1].docx
79K

EHR Standards for India - 2015 - Final Draft - 4 November 2015[1].pdf
897K

156

e-Governance Division
Department of Health & Family Welfare
Ministry of Health & Family Welfare
[illegible]vernment of India
mohfw.nic.in

ELECTRONIC HEALTH RECORD (EHR) STANDARDS FOR INDIA

OCTOBER 2015

Revised recommendations (over original August 2013 recommendations)

155

TABLE OF CONTENTS

Contents

Executive Summary 1
Standards at a Glance 3
Standards and Interoperability 7
Health Record IT Standards 9
Guidelines 15
Data Ownership of Health Records 17
Data Privacy and Security 22
Glossary 27
Contact Information 43

Executive Summary

INTRODUCTION

In September 2013 the Ministry of Health & Family Welfare (MoH&FW) notified the Electronic Health Record (EHR) Standards for India. The set of standards given therein were chosen from the best available and used standards applicable to Electronic Health Records from around the world keeping in view their suitability and applicability in India. The Committee constituted to recommend the standards drew from experts, practitioners, government officials, technologists, and industry. The notified standards were not only supported by professional bodies, regulatory bodies, stakeholders, but various technical and social commentators as well as being a step in the right direction. MoH&FW moved ahead with facilitating the adoption, as next steps, and in last two years the Ministry has made available standards like SNOMED CT free for use in country as well as appoint interim National Release Center (NRC) to handle this clinical terminology standard that is fast gaining widespread acceptance amongst the various healthcare IT stakeholder communities worldwide.

At the time of notifying the standards in September 2013, it was understood that the standards themselves will continue to evolve over time. Consequently, it was accepted that this notification will require revision from time to time. This becomes all the more necessary as understanding of those standards, their implementation and the expectations from the healthcare systems improve. Hence, MoH&FW constituted an expert group to review the earlier notified set of standards based on the experience and eyes firmly on the future. The set of standards provided herein represents the recommendations of the Expert Committee arrived at after deliberating on the various aspects of standardizations in healthcare record systems. The Committee also carefully examined the provisions of open standards and the guidelines as per the norms suggested by DeitY, MCIT, Government of India and recommended the standards given later in the document.

NEED FOR ELECTRONIC HEALTH RECORD

For a health record of an individual to be clinically meaningful it needs to be from conception or birth, at the very least. As one progresses through one's life, every record of every clinical encounter represents a health-related event in one's life. Each of these records may be insignificant or significant depending on the current problems that the person is suffering from. Thus, it becomes imperative that these records be available, arranged, and be clinically relevant to provide a summary of the various clinical events in the life of a person.

An Electronic Health Record (EHR) is a collection of various medical records that get generated during any clinical encounter or events. With rise of self-care and homecare devices and systems, meaningful healthcare data get generated 24x7 and also have long-term clinical relevance. The purpose of collecting medical records, as much as possible, are manifold – better and evidence based care, increasingly accurate and faster diagnosis that translates into better treatment at lower costs of care, avoid repeating unnecessary investigations, robust analytics including predictive analytics to support personalized care, improved health policy decisions based on better understanding of the underlying issues, etc., all translating into improved personal and public health.

EXECUTIVE SUMMARY

Without standards, a lifelong medical record is simply not possible, as different records from different sources spread across ~80+ years potentially needs to be brought meaningfully together. To achieve this, a set of pre-defined standards for information capture, storage, retrieval, exchange, and analytics that includes images, clinical codes and data is imperative.

STRATEGIC HIGHLIGHTS

This document provides a structured overview of the key EHR standards with respect to Indian healthcare system. For every aspect of data/information that is part of any healthcare record system has been addressed with a short guideline regarding implementation included. Various non-related recommendations from previous edition have been removed to better streamline the set of standards selected and achieve harmony among them. A detailed recommendation on the interoperability and standards, clinical informatics standards, data ownership, privacy and security aspects, and the various coding systems are given. The set of standards given in earlier edition has been updated with their latest versions as we move towards a better implementation.

LOOKING AHEAD

This document is a continuation of its earlier version, but in many ways reflects our growing confidence in path correctly chosen earlier – set of international and proven standards focused towards syntactic and semantic interoperability. The idea that any person in India can go to any health service provider/practitioner, any diagnostic center or any pharmacy and yet be able to access and have fully integrated and always available health records in an electronic format is not only empowering but also vision for efficient 21st century healthcare delivery.

In conclusion, it must be reiterated that these standards cannot be considered either in isolation or as "etched in stone for all eternity". These will need to undergo periodic review and update as necessary. Hence, this document must be a "living document".

152

Standards at a Glance

This section is provided for quick reference. Details are provided in the subsequent sections. N.B., this is a tentative list only.

S. No.	Type	Standard Name	Intended Purpose
1	Identification & Demographics	ISO/TS 22220:2011 Health Informatics – Identification of Subjects of Health Care	Basic identity details of patient
2		MDDS – Demographic (Person Identification and Land Region Codification) version 1.1	Complete demographic for interoperability with E-Governance systems
3	Patient Identifiers	UIDAI Aadhaar	Preferable identifier where available
4		Local Identifier	Identifier given within institution / clinic / lab
5		Government Issued Photo Identity Card Number	Identifier in conjunction with local in absence of Aadhaar
6	Architecture Requirements	ISO 18308:2011 Health Informatics – Requirements for an Electronic Health Record Architecture	System architectural requirements
7	Functional Requirements	ISO/HL7 10781:2015 Health Informatics - HL7 Electronic Health Records-System Functional Model Release 2 (EHR FM)	System functional requirements
8	Reference Model and Composition	ISO 13940 Health informatics - System of Concepts to Support Continuity of Care	Concepts for care, actors, activities, processes, etc.
9		ISO 13606 Health informatics - Electronic Health Record Communication (Part 1 through 3)	Information model architecture and communication
10		openEHR Foundation Models Release 1.0.2	Structural definition and composition
11	Terminology	SNOMED Clinical Terms (SNOMED CT)	Primary terminology
12	Coding System	Logical Observation Identifiers Names and Codes (LOINC)	Test, measurement, observations

STANDARDS AT A GLANCE

S. No.	Type	Standard Name	Intended Purpose
13		WHO Family of International Classifications (WHO-FIC) including ICD, ICF, ICHI, ICD-O	Classification and reporting
14	Imaging	Digital Imaging and Communications in Medicine (DICOM) PS3.0-2015	Image, waveform, audio/video
15	Scanned or Captured Records	JPEG lossy (or lossless) with size and resolution not less than 1024px x 768px at 300dpi	Image capture format
16		ISO/IEC 14496 - Coding of Audio-Visual Objects	Audio/Video capture format
17		ISO 19005-1 Document Management - Electronic Document File Format for Long-Term Preservation - Part 1: Use of PDF 1.4 (PDF/A-1)	Scanned documents format
18	Data Exchange	ANSI/HL7 V2.8.2-2015 HL7 Standard Version 2.8.2 - An Application Protocol for Electronic Data Exchange in Healthcare Environments	Event/Message exchange
19		ASTM/HL7 CCD Release 1 (basis standard ISO/HL7 27932:2009)	Summary Records exchange
20		ISO 13606-5:2010 Health informatics - Electronic Health Record Communication - Part 5: Interface Specification	EHR archetypes exchange [Also, refer to openEHR Service Model specification]
21		DICOM PS3.0-2015 (using DIMSE services & Part-10 media/files)	Imaging/Waveform Exchange
22	Other Relevant Standards	Bureau of Indian Standards and its MHD-17 Committee	Standards Development Organizations (SDOs)
23		ISO TC 215 set of standards	
24		IEEE/NEMA/CE standards for physical systems and interfaces	
25	Discharge/ Treatment Summary	Medical Council of India (MCI) under regulation 3.1 of Ethics	Composition as prescribed
26	E-Prescription	Pharmacy Practice Regulations, 2015 Notification No. 14-148/ 2012- PCI as specified by Pharmacy Council of India	Composition as prescribed
27	Personal Healthcare and medical Device Interface	IEEE 11073 health informatics standards and related ISO standards for medical devices	Device interfacing

STANDARDS AT A GLANCE

S. No.	Type	Standard Name	Intended Purpose
28	Data Privacy and Security	ISO/TS 14441:2013 Health Informatics – Security & Privacy Requirements of EHR Systems for Use in Conformity Assessment	Basis security and privacy requirements
29	Information Security Management	ISO/DIS 27799 Health informatics - Information Security Management in Health using ISO/IEC 27002	Overall information security management
30	Privilege Management and Access Control	ISO 22600:2014 Health informatics - Privilege Management and Access Control (Part 1 through 3)	Access control
31	Audit Trail and Logs	ISO 27789:2013 Health informatics - Audit trails for Electronic Health Records	Audit trail
32	Data Integrity	Secure Hash Algorithm (SHA) used must be SHA-256 or higher	Data Hashing
33	Data Encryption	Minimum 256-bits key length	Encryption key
34		HTTPS, SSL v3.0, and TLS v1.2	Encrypted connection
35	Digital Certificate	ISO 17090 Health informatics - Public Key Infrastructure (Part 1 through 5)	Digital certificates use and management

Note: *Where year of publication or version of standard (or its parts) is not provided explicitly, the latest published version of standard (or its parts) available from standard body as on the date of notification / circulation of this recommendation is to be used.*

STANDARDS AT A GLANCE

List of Supporting / Complimenting Standards

The following list is indicative and representative and not comprehensive or definitive. These standards are advised to be used where applicable and as required.

S. No.	Standard	Description
1	ISO 12967:2009	Health Informatics - Service Architecture (Parts 1 - 3)
2	ISO 13972:2015	Health Informatics - Detailed Clinical Models, Characteristics and Processes
3	ISO 20301:2014	Health Informatics - Health Cards - General Characteristics
4	ISO 21090:2011	Health Informatics - Harmonized Data Types for Information Interchange
5	ISO 8601:2004	Data elements and Interchange Formats - Information Interchange - Representation of Dates and Times
6	ISO 13119:2012	Health Informatics - Clinical Knowledge Resources - Metadata
7	ISO 22857:2013	Health Informatics – Guidelines on Data Protection to Facilitate Trans-Border Flows of Personal Health Data
8	ISO 21549-1:2013	Health Informatics — Patient Healthcard Data — Part 1: General Structure
9	ISO TS 14265:2011	Classification of Purposes for Processing Personal Health Information
10	ISO TS 27527:2010	Health Informatics – Provider Identification

Standards and Interoperability

INTEROPERABILITY STANDARDS

The primary aim of interoperability standards is to ensure syntactic (structural) and semantic (inherent meaning) interoperability of data amongst systems at all times. The need for that cannot be overstated, more so within healthcare information systems whose primary aim is to deliver life-long clinical care at all times so that the person being cared for is able to maintain his/her health.

The set of standards outlined in this document represents an incremental approach to adopting standards, implementation specifications; criteria to enhance the interoperability, functionality, utility, and security of health information technology; and to support its widespread adoption. It is to be kept in mind that these standards need to be flexible and modifiable to adapt to the demographic and resource variance observed in a country like India with its large population with diverse culture that is spread across a large region of varied geographical landscapes – hilly regions, river basins, desert, coast, etc. – many of which are remote and accessible with difficulty.

It is important to recognize that interoperability and standardization can occur at many different levels. To achieve interoperability, information models would need to be harmonized into a consistent representation.

In other cases, organizations may use the same information model, but use different vocabularies or code sets (for example, SNOMED CT or ICD10) within those information models. To achieve interoperability at this level, standardizing vocabularies, or mapping between different vocabularies may be necessary. For some levels, (such as the network transport protocol), an industry standard that is widely used (e.g. TCP/IP – Transmission Control Protocol and Internet Protocol) will likely be the most appropriate. Ultimately, to achieve true interoperability, it is anticipated that multiple layers – network transportation protocols, data and services descriptions, information models, and vocabularies and code sets – will need to be standardized and/or harmonized to produce an inclusive, consistent representation of the interoperability requirements.

It is further anticipated that using a harmonization process will integrate different representations of health care information into a consistent representation and maintain and update that consistent representation over time. For an information model, this process could include merging related concepts, adding new concepts, and mapping concepts from one representation of health care information to another. The need to support standardization of data and services descriptions and vocabularies and codes sets is appropriately addressed.

It is also recognized that a sustainable and incremental approach to the adoption of standards will require processes for harmonizing both current and future standards. This will allow the incremental updating of the initial set of standards, implementation specifications, and certification criteria and provide a framework to maintain them. The decision to adopt such updates will be informed and guided by recommendations from an appropriate authority such as the proposed National eHealth Authority (NeHA), Ministry of Health & Family Welfare or expert groups.

STANDARDS AND INTEROPERABILITY

GOALS

The goals of standards in electronic health record systems are:

- Promote interoperability and where necessary be specific about certain content exchange and vocabulary standards to establish a path forward toward semantic interoperability
- Support the evolution and timely maintenance of adopted standards
- Promote technical innovation using adopted standards
- Encourage participation and adoption by all vendors and stakeholders
- Keep implementation costs as low as reasonably possible
- Consider best practices, experiences, policies and frameworks
- To the extent possible, adopt standards that are modular and not interdependent.

146

Health Record IT Standards

IDENTIFICATION AND DEMOGRAPHIC INFORMATION OF PATIENT

Demographic information including a unique identifier is necessary in a health record system in order to capture identifying information as well as identifiers for linking other medical artifacts logically as well as physically. All health record systems must therefore adhere to the following standards for capturing information related to patient demography and identifiers:

1. ISO/TS 22220:2011 Health Informatics – Identification of Subjects of Health Care
2. MDDS – Demographic (Person Identification and Land Region Codification) version 1.1 from E-Governance Standards, Government of India

Implementation Guideline: Implementers must insure that health record application is able to capture all data fields as provided in the above two standards for completeness. It should also ensure that the system is able to interoperate (receive/import/send/export) all demographics information as provided in above two standards as per demand, i.e. when requested for demographics data in MDDS compliant format it should generate artefacts (file, message, etc.) as per that standard. Where codes related to location, authority, type of organization etc. are required, they should be taken from the MDDS-Demographic Standard.

A health record system must have provision to include patient identifiers of following types:

1. UIDAI Aadhaar Number (preferred where available)
2. Both of following in case Aadhaar is not available:
    2.1 Local Identifier (as per scheme used by HSP)
    2.2 Any Central or State Government issued Photo Identity Card Number

Implementation Guidelines:

1. Implementers must ensure that the Aadhaar number, where that is available, be used as the preferred identifier to serve as the unique health identifier. In case the Aadhaar number is not available, the system should allow a user to insert more than one (minimum two) identifiers for each patient along with its scope and provider (as given in above mentioned patient demography standards) in the system. In emergency situations where identity of patient cannot be confirmed or ascertained, temporary identifiers may be used (as per scheme used by HSP) and later confirmed identifiers may be inserted (while making earlier ones as inactive).
2. *Identification of Patient across EHR systems*: Due to lack of mandate for use of Aadhaar or any such alternative(s) national unique identifier, it is difficult to match patient records when exchanging them between two EHR systems. This may lead to situations where different combinations of local identifier and photo identity card numbers of the same person are used at different locations and/or in solutions. Thus, a single person may get to have different identities under which his/her records are captured. A conflict resolution process may be required to help resolve such cases. At this time, there is no direct solution available other than to use smart (possibly heuristic) algorithms to attempt to match records

without or with intervention/confirmation of a human supervisor. Such an algorithm may use name (phonetic or spelling), address (full or parts), date of birth / age, gender, or other such matching details to mark incoming or searched records as possible or exact match before amalgamation or subsequent use. ISV may additionally need to provide the ability to merge/demerge patients to support this process within their solutions.

ARCHITECTURE REQUIREMENTS AND FUNCTIONAL SPECIFICATIONS

A health record system must meet architectural requirements and functional specifications to remain faithful to the needs of service delivery, be clinically valid and reliable, meet legal and ethical requirements, and support good medical practices. Therefore, a health record system must conform to the following standards:

1. ISO 18308:2011 Health Informatics – Requirements for an Electronic Health Record Architecture
2. ISO/HL7 10781:2015 Health Informatics - HL7 Electronic Health Records-System Functional Model Release 2 (EHR FM)

Implementation Guideline: Above two standards, despite being extensive, are not full set of specifications and requirements to be met by a health record system or its many variants (PHR, etc.) or all possible use cases. The above mentioned standards are to be used as minimum set to be used within the scope of implementation as per relevance to the system being developed / deployed.

LOGICAL INFORMATION REFERENCE MODEL AND STRUCTURAL COMPOSITION

A health record system must accumulate observable data and information for all clinically relevant events and encounters. For this purpose, it is important to have common semantic and syntactic logical information model and structural composition for captured artefacts. Unless the data being captured is standardized, its communication and understanding may not be same across systems. Therefore, a health record system must conform to the following standards:

1. ISO 13940 Health Informatics - System of Concepts to Support Continuity of Care
2. ISO 13606 Health Informatics - Electronic Health Record Communication (Part 1 though3)
3. openEHR Foundation Models Release 1.0.2

    3.1 Required Model Specifications: Base Model, Reference Model, Archetype Model
    3.2 Optional Model Specifications: Service Model, Querying, Clinical Decision Support

Implementation Guideline: The ISO 13940 (also known as CEN ContSys) is to be generally used for purpose of modelling and describing concept system and organize information objects. While ISO 13606 set of standards are basic reference model and related specifications, openEHR provides ISO 18308 conformant platform-independent implementation harmonized with ISO 13606 standard. Implementers are free to design internal structures, databases, and user interfaces as per the requirements and technology platforms but structural composition for clinical data/information artefact must be logically similar to Reference Model given in above standards. A health record system implementation must make its openEHR compliant Operational Templates (OPT) freely available and accessible in required format.

144

MEDICAL TERMINOLOGY AND CODING STANDARDS

In order to have semantic interoperability between different health record systems, it is necessary to follow a common terminology and coding system standards to express unambiguous meaning of data captured, stored, transmitted, and analyzed. It is also important to have these terminologies and codes in computer process-able format to aid automation and ensure that data is in an analyzable state at all times. Therefore, a health record system must conform to the following standards:

1. Primary Terminology: IHTSDO - SNOMED Clinical Terms (SNOMED CT)

Implementation Guideline: A health record system must use SNOMED CT as the primary internal encoding system for all clinically relevant, including dental, nursing, substance/drugs, information. IHTSDO SNOMED CT code shall also be used while communicating clinical information to other health record systems. SNOMED CT concept codes (as pre-coordinated or as post-coordinated expressions) are to be used for all hierarchies covered under the standard unless otherwise provided in this document. It shall also be the coding system that must be used internally in other information storage and communication standards such as openEHR archetypes, HL7, DICOM, etc. IHTSDO releases SNOMED CT twice annually.

2. Test, Measurement and Observation Codes: Regenstrief Institute - Logical Observation Identifiers Names and Codes (LOINC)

Implementation Guideline: LOINC coding is to be used for processing results and reports with Laboratory and Imaging Information Systems. N.B.: SNOMED CT to LOINC coding interchange map is available from IHTSDO and Regenstrief Institute.

3. Classification Codes: WHO Family of International Classifications (WHO-FIC)

    3.1 WHO ICD-10: International Classification of Diseases (ICD) and its derivative classifications
    3.2 WHO ICF: International Classification of Functioning, Disability and Health (ICF)
    3.3 International Classification of Health Interventions (ICHI)
    3.4 International Classification of Diseases for Oncology (ICD-O)

Implementation Guideline: WHO FIC codes are primarily used for aggregated information and statistical/epidemiological analysis for public health purposes derived from health records that contain patient care related information as well as information that is crucial for management, health financing and general health system administration. While SNOMED CT is to be used by health record systems for terminology, generated classification-based reports may require the use of WHO FIC codes. Classification based reporting, for statistical or regulatory purposes, may continue to use WHO FIC codes as mandated by the health regulatory, intelligence, and various research bodies. N.B.: SNOMED CT to ICD-10 coding interchange map is available from IHTSDO and WHO.

DATA STANDARDS FOR IMAGE, MULTIMEDIA, WAVEFORM, DOCUMENT

A health record system stores data records and files of various types in support of clinical functions. These data elements serve the purpose of documentary records of various diagnostic and prescriptive data or information generated. Therefore, a health record system must conform to the following standards for such data:

1. NEMA Digital Imaging and Communications in Medicine (DICOM) PS3.0-2015

Implementation Guideline: NEMA DICOM PS3.0-2015 is a comprehensive standard for handling and managing image (series or single), waveforms (such as those in ECG/EEG), audio (such as those in digital-stethoscope) and video (such as those in endoscope, ultrasound) data in medicine. A health record implementation is required to implement relevant DICOM Information Object Definitions (IODs) for supported data types in Part-10 compliant files. Where required and relevant, other features of standard such as services, display, print, and workflow may be implemented.

2. Scanned or Captured Records:

   2.1 Image: JPEG lossy (or lossless) with size and resolution not less than 1024px x 768px at 300dpi
   2.2 Audio/Video: ISO/IEC 14496 - Coding of Audio-Visual Objects
   2.3 Scanned Documents: ISO 19005-1 Document Management - Electronic Document File Format for Long-Term Preservation - Part 1: Use of PDF 1.4 (PDF/A-1)

Implementation Guideline: The above mentioned standards are to be used for documentary data (scan for prescription, summaries, etc.) and data captured through traditionally non-DICOM compliant sources like picto-micrographs, pathological photographs, photographs of intramural and extramural lesions, etc. All data formats that can be converted into relevant DICOM format should be, as relevant, converted and communicated as secondary captured DICOM format. It may be noted that while no maximum image resolution has been prescribed, a sufficiently acceptable limit may be used to avoid unnecessarily large file that do not aid in correspondingly better diagnosis or analysis.

DATA EXCHANGE STANDARDS

A health record system has to operate in a larger ecosystem of other components with which it must share or communicate data in order to capture and provide as comprehensible medical information as is practical. A health record system must therefore conform to the following standards:

1. Event/Message Exchange: ANSI/HL7 V2.8.2-2015 HL7 Standard Version 2.8.2 - An Application Protocol for Electronic Data Exchange in Healthcare Environments
2. Summary Records Exchange: ASTM/HL7 CCD Release 1 (basis standard ISO/HL7 27932:2009)
3. EHR Archetypes: ISO 13606-5:2010 Health informatics - Electronic Health Record Communication - Part 5: Interface Specification [Also, refer to openEHR Service Model specification]
4. Imaging/Waveform Exchange: NEMA DICOM PS3.0-2015 (using DIMSE services& Part-10 media/files)

Implementation Guideline: Implementation of exchange standards is expected to be at least for the scope of data captured or retained by the health record system. To explain further, full implementation of ANSI/HL7 V2.8.2 for each event and message is not required in health record systems but minimum implementation supporting the types of events and messages relevant to the system is required. Similarly,

(42)

implementation/support of DICOM DIMSE C-Store and/or C-FIND/C-GET service is expected for IODs supported by health record system whereas implementation of WADO could be optional.

OTHER STANDARDS RELEVANT TO HEALTHCARE SYSTEMS

Healthcare record systems need to co-exist within a larger ecosystem with various other systems. It is important for all systems within a healthcare setup to adhere to relevant standards. While standards related to such systems are not within the scope of this document, as a general rule, standards created or ratified by following Standard Development Organizations (SDOs) should be used:

1. Bureau of Indian Standards and its MHD-17 Committee
2. ISO TC 215 set of standards
3. IEEE/NEMA/CE standards for physical systems and interfaces

Implementation Guideline: To help the implementers, an indicative list of such standards is provided in the "Standards at a Glance" section above. BIS approved standards shall be preferred for implementation.

DISCHARGE/TREATMENT SUMMARY FORMAT

Implementers must ensure that the logical information model includes data elements to satisfy requirements of the format for Medical Records as specified by Medical Council of India (MCI) under regulation 3.1 of ethics. The printed reports will need to be in the MCI prescribed format whenever any discharge or treatment summary is prepared.

E-PRESCRIPTION

Pharmacy Council of India (PCI) has, in its recent regulation (Pharmacy Practice Regulations, 2015 Notification No. 14-148/ 2012- PCI), provided the definition of the term under Section 2(j) that the term 'Prescription' includes the term 'electronic direction'. Implementers must therefore ensure that the logical information model includes data elements to satisfy requirements of the format for Medical Prescription as specified by the Pharmacy Council of India. The printed prescription will need to be in the PCI prescribed format whenever any medical prescription meant for drug dispensing is prepared. For the purpose of e-Prescription, implementers must ensure that the electronic version is digitally signed by a registered medical practitioner, and its non-repudiation is ensured at all times. The pharmacists shall be able to print a copy of e-Prescription in the required format along with other relevant digital authentication details.

PERSONAL HEALTHCARE AND MEDICAL DEVICES INTERFACING

Where not covered under relevant data exchange standards, it is recommended that IEEE 11073 health informatics standards and related ISO standards for medical devices be followed as appropriate whenever any personal healthcare/medical device is interfaced with the EMR system for the purpose of clinical data exchange, retrieval, storage, etc.

HEALTH RECORD IT STANDARDS

PRINCIPLES OF DATA CHANGE

The data once entered into a health record system must become immutable. The healthcare provider may have the option to re-insert/append any record in relation to the medical care of the patient as necessary with a complete audit trail of such change maintained by system. Alteration of the previously saved data should not be permitted. No *update* or *update like* command shall be accessible to user or administrator to store a medical record or part thereof. Any record requiring revision should create a new medical record containing the changed/appended/modified data of earlier record. This record shall then be stored and marked as ACTIVE while rendering the previous version(s) of the same record marked INACTIVE. The data will thus be immutable. A strict audit trail shall be maintained of all activities at all times that may be suitably reviewed by an appropriate authority like auditor, legal representatives of the patient, the patient, healthcare provider, privacy officer, court appointed/authorized person, etc.

As-Is Principal:

The data captured through the devices is usually in a certain format whereas the data given by the doctor as file may be in some different format. These data provided / included in the system is to be treated as sacrosanct. The As-Is Principal requires that the data captured in the first instance should be retrievable at any given point of time later in the same format, clarity, size and detail as it was provided in the beginning.

It effectively means that the system is not allowed to make any changes either to the data or its format or its nature at any point other than the creation time for any reason. However, if it is required that the data needs to be altered either to carry some additional information at some later point, like annotation on images, or correction of errors of omission or commission, etc., it must be done on a copy of the original data, keeping the original data intact, and marking the updated version as active while marking the previous version inactive. The modified data will become part of the EHR/EMR.

Informed Format Change:

Whenever, the data, its format or its nature needs to be changed within the system, it must be done with the explicit consent of the doctor / technician / person that is entering or managing the data. This explicit consent can also be taken from a set of preferences already set by the user or the administrator / root of the system. In such preference based consent, there is no need to prompt the user for permission at each insertion point.

Also, in case the system is set to change format or nature of data automatically by setting of preferences, it must be made sure that the rule of conversion is declared in the Standard Operating Procedure (SOP) of site/application.

(40)

Guidelines

HARDWARE

- The IT hardware used should meet (and preferably be better than) the optimal requirements specified by the software (to be) used.
- The medical and IT hardware used must meet the relevant applicable specifications from BIS, NEMA, IEEE, ISO, CE, RoHS, EnergyStar, apart from Medical and IT standards for the equipment.
- A backup or data preservation mechanism should be considered. Data capacity should be planned to meet the storage requirement as per the mandated rule/law.
- System redundancy at various levels (disk, power, network, etc.) should be planned to meet the organizational system availability requirement.
- Network and data security should be planned, implemented, and periodically audited. Please see section on Security and Privacy for the various requirements and functions that need to be supported and implemented.
- Hardware should be checked periodically for correctness and completeness of operation expected from them. An appropriate maintenance cycle should be planned and rigorously followed.
- Planned and expected Capacity and Quality requirement of the organization should be met by the hardware used. Periodic updates and upgrades should be carried out to meet the requirements.

NETWORKING AND CONNECTIVITY

- Should be able to harness any telecommunications-related connectivity like the Internet, LAN, WAN, WAP, CDMA, GSM or even Cloud Computing that will permit the various EMRs of an individual to be integrated into a single lifelong electronic health record
- As far as is practical and affordable, the connectivity medium chosen should be reliable and fast enough to sustain a secure data exchange for the period expected for transaction of records and data. The speed of the connectivity medium should be chosen from among available options so as to provide an acceptable user experience and not cause software/system fault due to delays/noise/failure.
- Should be able to ensure that data exchange is performed in a secure manner to ensure data validity and non-repudiability
- The data exchange must further ensure that data integrity is maintained at all times

SOFTWARE STANDARDS

The software for capturing, storing, retrieving, viewing, and analyzing healthcare records should:

- Conform to the specified standards
- Satisfy specified requirements
- Be Interoperable, especially in terms of syntax and semantics of the information being exchanged

129

GUIDELINES

- Should be able to ensure user authentication and authorization
- Should be able to support privacy, secrecy and audit trail
- Possess advanced search, merge, and demerge functionality to ensure that duplicates are robustly resolved
- Should be able to support conception-to-current/most recent medical records of a person (as relevant to scope of application)
- Should be able to support digital archiving and retrieval of medical records after the death of a person for the total duration as specified by Government of India from time to time
- Should be able to construct a medical/clinical summary based on available records from the very first visit to current/most recent
- Preferably be able to support rapid data capture-storage-retrieval-display of data

HEALTH RECORD IN MOBILE DEVICES

As people become more mobile and travel becomes more accessible, patients will increasingly expect the healthcare record system to provide essential health information over mobile devices, which will give their treating clinician basic information like, medical condition, drug/allergy information etc. Demographics, insurance info, medications, allergy and alerts, and vital signs are some of the records that are recommended to be provided in at least read-only manner and to the extent relevant for emergency care and quick reference. It is also possible that certain clinical (BP, temperature, glucose count) and lifestyle (steps walked, distance run, sleep duration and quality) related information will additionally be provided by the patient thereby providing vital clues and information on the overall wellbeing of patient.

In the specific regard of design and usability of such applications, m-governance guidelines of DeitY, Ministry of Communication & Information Technology, Government of India shall be applicable. (http://www.deity.gov.in/content/framework-mobile-governance).

138

Data Ownership of Health Records

THE ETHICAL, LEGAL, SOCIAL ISSUES (ELSI) GUIDELINES

For the purposes of these recommendations, the term "privacy" shall mean that only those person or person(s) including organizations duly authorized by the patient may view the recorded data or part thereof. The term "security" shall mean that all recorded personally identifiable data will at all times be protected from any unauthorized access, particularly during transport (e.g. from healthcare provider to provider, healthcare provider to patient, etc.). The term "trust" shall mean that person, persons or organizations (doctors, hospitals, and patients) are those who they claim they are.

The following approaches are to be adopted wherever applicable to address the aspects that the terms mentioned above refer to:

- Privacy would refer to authorization by the owner of the data (the patient)
- Security would have as components both public and private key encryption; the encryption techniques used in transit and at rest need to be through different methodologies.
- Trust would be accepted whenever a trusted third party confirms identity

PROTECTED HEALTH INFORMATION

Protected Health Information (PHI) would refer to any individually identifiable information whether oral or recorded in any form or medium that (1) is created, or received by a stakeholder; and (2) relates to past, present, or future physical or mental health conditions of an individual; the provision of health care to the individual; or past, present, or future payment for health care to an individual.

Electronic Protected Health Information (ePHI) would refer to any protected health information (PHI) that is created, stored, transmitted, or received electronically. Electronic protected health information includes any medium used to store, transmit, or receive PHI electronically.

As per the Information Technology Act 2000, Data Privacy Rules, refer to 'sensitive personal data or information' (Sensitive Data) as the subject of protection, but also refer, with respect to certain obligations, to 'personal information'. Sensitive Data is defined as a subset of 'personal information'. Sensitive Data is defined as personal information that relates to:

1. Passwords
2. Financial information such as bank account or credit card or debit card or other payment instrument details
3. Physical, psychological and mental health condition
4. Sexual orientation
5. Medical records and history
6. Biometric information

DATA OWNERSHIP OF HEALTH RECORDS

7. Any detail relating to (1) – (6) above received by the body corporate for provision of services
8. Any information relating to (1) – (7) that is received, stored or processed by the body corporate under a lawful contract or otherwise

DATA OWNERSHIP

- The physical or electronic records, which are generated by the healthcare provider, are held in trust by them on behalf of the patient
- The contained data which are the sensitive personal data of the patient is owned by the patient herself.
- The medium of storage or transmission of such electronic medical record will be owned by the healthcare provider.
- The "sensitive personal information (SPI) and personal information (PI)" of the patient is owned by the patient themselves. Refer to IT Act 2000 for the definition of SPI and PI.

DATA ACCESS AND CONFIDENTIALITY

- Regulations are to be enforced to ensure confidentiality of the recorded patient/medical data and the patient should have a control over this.
- Patients will have the sufficient privileges to inspect and view their medical records without any time limit. Patient's privileges to amend data shall be limited to correction of errors in the recorded patient/medical details. This shall need to be performed through a recorded request made to the healthcare provider within a period of 30 days from the date of discharge in all inpatient care settings or 30 days from the date of clinical encounter in outpatient care settings. An audit of all such changes shall be strictly maintained. Both the request and audit trail records shall be maintained within the system.
- Patients will have the privileges to restrict access to and disclosure of individually identifiable health information and need to provide explicit consent, which will be audited, to allow access and/or disclosures.
- All recorded data will be available to care providers on an 'as required on demand' basis

DISCLOSURE OF PROTECTED / SENSITIVE INFORMATION

- For use in treatment, payments and other healthcare operations: In all such cases, a general consent must be taken from the patient or next of kin, etc. as defined by applicable laws by MCI.
- Fair use for non-routine and most non-health care purposes: a specific consent must be taken from the patient; format as defined by MCI.
- For certain specified national priority activities, including notifiable/communicable diseases, the health information may be disclosed to appropriate authority as mandated by law without the patient's prior authorization
- Instances where use and disclosure without individual authorization will be possible are as follows:

136

  - Complete record with all identifiers in an "as-is" state, on production of court order
  - Totally anonymized data, where the anonymization process involves the complete removal of all information that allows the identification of the patient. (List of such personally identifiable information is provided below)

RESPONSIBILITIES OF A HEALTHCARE PROVIDER

- Protect and secure the stored health information, as per the guidelines specified in this document
- While providing patient information, remove patient identifying information (as provided in the list below), if it is not necessary to be provided
- Will ensure that there are appropriate means of informing the patient of policies relating to her/his rights to health record privacy
- Document all its privacy policies and ensure that they are implemented and followed. This will include:
  - Develop internal privacy policies
  - Designate a privacy officer (preferably external, may be internal) who will be responsible for implementing privacy policies, audit and quality assurance
  - Provide privacy training to all its staff

PRIVILEGES OF PATIENT OR PERSONAL REPRESENTATIVE

Patient will have the privilege to appoint a personal representative to carry out the activities detailed below.

- Patients will have the privilege to ask for a copy of its medical records held by a healthcare organization.
- Patients will have the privilege to request a healthcare organization that stores/maintains his/her medical records, to withhold specific information that he/she does not want disclosed to other organizations or individuals.
- Patient can demand information from a healthcare provider on the details of disclosures performed on the patient's medical records for any reason whatsoever

DENIAL OF INFORMATION

Healthcare provider will be able to deny information to a patient or representative or third party, in contravention of normal regulations, if in the opinion of a licensed healthcare professional the release of information would endanger the life or safety of the patients and others. This will include but not be limited to as follows:

- Information obtained from an anonymous source under a promise of confidentiality.
- Psychotherapy notes.
- Information compiled for civil, criminal or administrative action.

DATA OWNERSHIP OF HEALTH RECORDS

ELECTRONIC MEDICAL RECORDS PRESERVATION

Preservation of medical records assume significant importance in view of the fact that an electronic health record of a person is an aggregation of all electronic medical records of the person from the very first entry till date. Hence, all records must compulsorily be preserved and not destroyed during the life-time of the person, ever.

Upon the demise of the patient where there are no court cases pending, the records can be removed from active status and turned to inactive status. ISVs are free to decide when to make a record inactive, however, it is preferable to follow the "three (3) year rule" where all records of a deceased are made inactive three (3) years after death.

It is however preferred and ISVs are strongly encouraged to ensure that the records are never be destroyed or removed permanently. The health of the blood relatives and natural descendants of the person can be strongly influenced by the health of the person and on-demand access to these may prove to be hugely useful in the maintenance of the health of the relations.

Furthermore, analysis of health data of all persons is expected to greatly benefit in the understanding of health, disease processes and the amelioration thereof.

With rapid decline in costs of data archiving coupled with the ability to store increasing amounts of data that may be readily accessible, continued maintenance of such data is not expected to lead to any major impact on the overall system maintenance and use.

PATIENT IDENTIFYING INFORMATION

Data are "individually identifiable" if they include any of the under mentioned identifiers for an individual or for the individual's employer or family member, or if the provider or researcher is aware that the information could be used, either alone or in combination with other information, to identify an individual. These identifiers are as follows:

- Name
- Address (all geographic subdivisions smaller than street address, and PIN code)
- All elements (except years) of dates related to an individual (including date of birth, date of death, etc.)
- Telephone, cell (mobile) phone and/or Fax numbers
- Email address
- Bank Account and/or Credit Card Number
- Medical record number
- Health plan beneficiary number
- Certificate/license number
- Any vehicle or other any other device identifier or serial numbers
- PAN number

134

DATA OWNERSHIP OF HEALTH RECORDS

- Passport number
- AADHAAR card
- Voter ID card
- Fingerprints/Biometrics
- Voice recordings that are non-clinical in nature
- Photographic images and that possibly can individually identify the person
- Any other unique identifying number, characteristic, or code

APPLICABLE LEGISLATION

The existing Indian laws including IT Act 2000 and their amendments from time to time would prevail. (http://deity.gov.in/content/information-technology-act-2000).

158

DATA PRIVACY AND SECURITY

Data Privacy and Security

SECURITY OF ELECTRONIC HEALTH INFORMATION:

The Privacy Standards and the Security Standards are necessarily linked. Any health record system requires safeguards to ensure that the data is available when needed and that information is not used, disclosed, accessed, altered, or deleted inappropriately while being stored or retrieved or transmitted. The Security Standards work together with the Privacy Standards to establish appropriate controls and protections. Health sector entities that are required to comply with the Privacy Standards also must comply with the Security Standards.

Organizations must consider several factors when adopting security measures. How a healthcare provider satisfies the security requirements and which technology it decides to use are business decisions left to the individual organizations. In deciding what security measures to adopt, an organization must consider its size, complexity, and capabilities; it's technical infrastructure, hardware, and software security capabilities; the cost of particular security measures; and the probability and degree of the potential risks to the ePHI it stores, retrieves and transmits.

PURPOSE OF THE SECURITY STANDARDS

The security standards require healthcare providers to implement reasonable and appropriate *administrative*, *physical*, and *technical* safeguards to:

- ensure the confidentiality, integrity, and availability of all the e-PHI they create, transmit, receive, or maintain
- protect against reasonably anticipated threats or hazards to the security or integrity of their e-PHI
- protect against uses or disclosures of the e-PHI that are not required or permitted under the Privacy Standards
- ensure their workforce will comply with their security policies and procedures

TECHNICAL STANDARDS

To protect the ePHI handles by a healthcare provider, the provider must implement technical safeguards as part of its security plan. Technical safeguards refer to using technology to protect ePHI by controlling access to it. Therefore, they must address the following standards focusing on the following functionalities. It is worth noting that they will need to use an EHR/EMR solution that is able to successfully and robustly demonstrate the possession and working of these functionalities.

The basic requirements for security and privacy are provided in following standard:

1. ISO/TS 14441:2013 Health Informatics – Security & Privacy Requirements of EHR Systems for Use in Conformity Assessment

132

Authentication:

- Locally within the system the fact that a person or entity seeking access to electronic health information is indeed the one as claimed and is also authorized to access such information must be verifiable.
- Across the network, however extensive it might be, the fact that a person or entity seeking access to electronic health information across a network is the one claimed and is authorized to access such information in accordance with the standard specified in this document must be verifiable.

Automatic log-off: An electronic session after a predetermined time of inactivity must be forcibly terminated. To log in back, the user will have to initiate a new log in session. However, for the sake of ergonomics, it is recommended that the unsaved state of the system at the time of automatic log-off be saved and presented back to the user for further action. This should be a user-specific feature.

The advisory standard for overall information security management in health is:

2. ISO 27799 Health informatics - Information Security Management in Health using ISO/IEC 27002

Implementation Guideline: The ISO 27799 is provided as a basic advisory standard for security management. Other security management and standard / practices / guidelines given by Law (such as IT Act 2000 and amendments) or regulatory / statutory / certification bodies (such as National Accreditation Board for Hospitals & Health care Providers (NABH)) should be taken in consideration when designing and/or implementing health record system.

Access control: The solution must assign a unique name and/or number for identifying and tracking user identity and establish controls that permit only authorized users to access electronic health information. In cases of emergency where access controls need to be suspended in order to save a live, authorized users (who are authorized for emergency situations) will be permitted to have unfettered access electronic health information for the duration of the emergency with the access remaining in force during the validity of the emergency situation.

Access Privileges: Ideally only clinical care providers should have access rights to a person's clinical records. However, different institutional care providers have widely varying access privileges specified that are institution-specific. No country-wide standards can be specified for this at least at this point in time.

For privilege management and access control, following standards may be used:

3. ISO 22600:2014 Health informatics - Privilege Management and Access Control (Part 1 through 3)

Implementation Guideline: The ISO 22600 set of standards is provided as an advisory standard for policy based access control. For the purpose of privilege management, rule / policy based access is expected to give better control and flexibility in defining and enforcing access control. Access control mechanisms such as

131

DATA PRIVACY AND SECURITY

Role Based, Policy Based, or singular user (applicable in case of mobile based PHR) are acceptable as long as conformant to applicable data security law(s) and rules as well as policy of the organization where implemented.

Audit log:

- All actions related to electronic health information in accordance with the standard specified in this document including viewing should be recorded.
- Based on user-defined events must be provided.
- All or a specified set of recorded information upon request or at a set period of time must be electronically displayed and printed.

The advisory standard for audit trail / log in health record system is:

4. ISO 27789:2013 Health informatics - Audit Trails for Electronic Health Records

Integrity:

- During data transit the fact that the electronic health information has not been altered in transit in accordance with the standard specified in this document must be verifiable.
- Detection of events – all alterations and deletions of electronic health information and audit logs, in accordance with the standard specified in this document must be detected.
- Appropriate verification that electronic health information has not been altered in transit shall be possible at any point in time. A secure hashing algorithm must be used to verify that electronic health information has not been altered in transit and it is recommended that the Secure Hash Algorithm (SHA) used must be SHA-256 or higher.

Encryption:

- Generally, all electronic health information must be encrypted and decrypted as necessary according to organization defined preferences in accordance with the best available encryption key strength (minimum 256-bits key).
- During data exchange all electronic health information must be suitably encrypted and decrypted when exchanged in accordance with an encrypted and integrity protected link.
- All actions related to electronic health information must be recorded with the date, time, patient identification, and user identification whenever any electronic health information is created, modified (non-clinical data only), deleted (stale and non-clinical data only), or printed; and an indication of which action(s) took place must also be recorded.

130

- A cross-enterprise secure transaction that contains sufficient identity information such that the receiver can make access control decisions and produce detailed and accurate security audit trails must be used within the system.
- Secure Transmission standards and mechanisms must be used to allow access to health information as well as transmit data from one application / site to another. For this purpose HTTPS, SSL v3.0, and TLS v1.2 standards should be used. Please refer to relevant IETF, IEEE, ISO, and FIPS standards for same.

Digital Certificates:

Use of Digital Certificates for identification and digital signing is recommended in health record system. Health record system must use following standard where digital certificates are used:

5. ISO 17090 Health informatics - Public Key Infrastructure (Part 1 through 5)

ADMINISTRATIVE SAFEGUARDS STANDARDS

The Administrative Safeguards require healthcare providers to develop and implement a security management process that includes policies and procedures that address the full range of their security vulnerabilities. Being administrative in nature, these need to be internally designed and developed as standard operating procedure (SOP) that must be published for all users to see and adhere to. Conformance to adherence may be delegated to the Privacy Officer detailed in the Data Ownership chapter above. To comply with the Administrative Safeguards, a healthcare provider must implement the following standards.

- The security management process standard, to prevent security violations;
- Assigned security responsibility, to identify a security officer;
- Workforce security, to determine e-PHI user access privileges;
- Information access management, to authorize access to e-PHI;
- Security awareness training, to train staff members in security awareness;
- Security incident procedures, to handle security incidents;
- Contingency plan, to protect e-PHI during an unexpected event; and
- Evaluation, to evaluate an organization's security safeguards.

PHYSICAL SAFEGUARDS STANDARDS

Physical safeguards are security measures to protect a healthcare provider's electronic information systems, related equipment, and the buildings housing the systems from natural and environmental hazards, and unauthorized intrusion. Healthcare providers must fulfill the following four standards. However, since most of the implementation specifications in this category are addressable, healthcare providers have flexibility in determining how to comply with the requirements as long as these are internally designed and developed as per the relevant SOP and published for all users to see and adhere to. Conformance to adherence may be delegated to the Privacy Officer detailed in the Data Ownership chapter above.

DATA PRIVACY AND SECURITY

The required physical standards are:

- The facility access control standard, to limit actual physical access to electronic information systems and the facilities where they're located;
- The workstation use standard, to control the physical attributes of a specific workstation or group of workstations, to maximize security;
- The workstation security standard, to implement physical safeguards to deter the unauthorized access of a workstation; and
- The device and media controls standard, to control the movement of any electronic media containing ePHI from, to or within the facility.

Glossary

The various terms, including acronyms, are explained from a conceptual point and may not be the formal definitions.

ADSL (Asymmetric Digital Subscriber Line): A type of DSL that uses copper telephone lines to transmit data faster than a traditional modem. ADSL only works within short distances because it uses high frequencies with short signals.

Allergy List: This is a list of all the patient's allergies.

Allopathic, Allopathy: Defined as relating to or being a system of medicine that aims to combat disease by using remedies (as drugs or surgery) which produce effects that are different from or incompatible with those of the disease being treated

Ambulatory care: Any medical care delivered on an outpatient basis.

ANM: Auxiliary Nurse Midwife

Archetype: Basically an information model, it is a computable expression of a domain content model in the form of structured constraint statements, based on a reference (information) model. Within the openEHR paradigm, archetypes are based on the openEHR reference model. Archetypes are all expressed in the same formalism. In general, they are defined for wide re-use, however, they can be specialized to include local particularities. They can accommodate any number of natural languages and terminologies.

Artefact: An object made by a human being, typically one of cultural or historical interest. In healthcare IT context, an artefact is any item such as a document, file or drawing, etc. that is generated for use as a reference material or inside a system.

ASHA: Accredited Social Health Activist is usually a literate 25 – 45 year old married/ widowed/ divorced lady selected from the village itself and accountable to it and trained to work as an interface between the community and the public health system. This is position is one of the key components of the National Rural Health Mission aimed at providing every village in the country with a trained female community health activist

ATC: Anatomical Therapeutic Chemical Classification System, controlled by the WHO Collaborating Centre for Drug Statistics Methodology (WHOCC), is used for drug classification.

Authentication: The verification of the identity of a person or process.

Authorization: Any document designating any permission. Authorization or waiver of authorization for the use or disclosure of identifiable health information for research (among other activities) is required. The authorization must indicate if the health information used or disclosed is existing information and/or new information that will be created. The authorization form may be combined with the informed consent form, so that a patient need sign only one form. An authorization must include the following specific elements: a

description of what information will be used and disclosed and for what purposes; a description of any information that will not be disclosed, if applicable; a list of who will disclose the information and to whom it will be disclosed; an expiration date for the disclosure; a statement that the authorization can be revoked; a statement that disclosed information may be re-disclosed and no longer protected; a statement that if the individual does not provide an authorization, she/he may not be able to receive the intended treatment; the subject's signature and date.

AYUSH: Ayurveda, Yoga, Unani, Siddha and Homeopathy. Falls under the broad category of Indian Systems of Medicines and Homoeopathy (ISM&H) governed by Ministry of Health and Family Welfare, Government of India

[C]

CCD (Continuity of Care Document): A joint effort of HL7 International and ASTM. CCD fosters interoperability of clinical data by allowing physicians to send electronic medical information to other providers without loss of meaning and enabling improvement of patient care. CCD is an implementation guide for sharing Continuity of Care Record (CCR) patient summary data using the HL7 Version 3 Clinical Document Architecture (CDA), Release 2. It establishes a rich set of templates representing the typical sections of a summary record, and these same templates for vital signs, family history, plan of care, and so on can then be used for establishing interoperability across a wide range of clinical use cases.

CDT: Common Dental Terminology

Chain of Trust Agreement: A contract needed to extend the responsibility to protect health care data across a series of sub-contractual relationships.

Chief Complaint (CC), Reason for Consultation (RFC), Reason of Visit (ROV): for recording a patient's disease symptoms.

Client/Server Architecture: An information-transmission arrangement, in which a client program sends a request to a server. When the server receives the request, it disconnects from the client and processes the request. When the request is processed, the server reconnects to the client program and the information is transferred to the client. This usually implies that the server is located on site as opposed to the ASP (Application Server Provider) architecture.

Clinical Care Provider: Personnel or entities directly related to providing clinical care to patient.

Clinical Data Repository (CDR): A real-time database that consolidates data from a variety of clinical sources to present a unified view of a single patient. It is optimized to allow clinicians to retrieve data for a single patient rather than to identify a population of patients with common characteristics or to facilitate the management of a specific clinical department.

Clinical Decision Support System (CDSS): A clinical decision support system (CDSS) is software designed to aid clinicians in decision making by matching individual patient characteristics to computerized knowledge bases for the purpose of generating patient-specific assessments or recommendations.

GLOSSARY

Clinical Establishment: Clinical establishment means (1) a hospital, maternity home, nursing home, dispensary, clinic, sanatorium or an institution by whatever name called that offers services, facilities requiring diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognized system of medicine established and administered or maintained by any person or body of persons, whether incorporated or not; or (2) a place established as an independent entity or part of an establishment referred to above, in connection with the diagnosis or treatment of diseases where pathological, bacteriological, genetic, radiological, chemical, biological investigations or other diagnostic or investigative services with the aid of laboratory or other medical equipment, are usually carried on, established and administered or maintained by any person or body of persons, whether incorporated or not. (Clinical Establishment Act – CEA 2010)

Clinical Guidelines (Protocols): Clinical guidelines are recommendations based on the latest available evidence for the appropriate treatment and care of a patient's condition.

Clinical Messaging: Communication of clinical information within the electronic medical record to other healthcare personnel.

Coded Data: Data are separated from personal identifiers through use of a code. As long as a link exists, data are considered indirectly identifiable and not anonymous or anonymized.

Code Set: Any set of codes used to encode data elements, such as tables of terms, medical concepts, medical diagnostic codes, or medical procedure codes. This includes both the codes and their descriptions.

Coding: A mechanism for identifying and defining physicians' and hospitals' services. Coding provides universal definition and recognition of diagnoses, procedures and level of care. Coders usually work in medical records departments and coding is a function of billing. Medicare fraud investigators look closely at the medical record documentation, which supports codes and looks for consistency. Lack of consistency of documentation can earmark a record as "up-coded" which is considered fraud. A national certification exists for coding professionals and many compliance programs are raising standards of quality for their coding procedures.

Computer-Based Patient Record (CPR): A term for the process of replacing the traditional paper-based chart through automated electronic means; generally includes the collection of patient-specific information from various supplemental treatment systems, i.e., a day program and a personal care provider; its display in graphical format; and its storage for individual and aggregate purposes. CPR is also called "digital medical record" or "electronic medical record".

Computerized Patient Record (CPR): Also known as an EMR or EHR.A patient's past, present, and future clinical data stored in a server.

Computerized Physician Order Entry (CPOE): A system for physicians to electronically order labs, imaging and prescriptions

GLOSSARY

CPT (Current Procedural Terminology) Code: A recognizable five-digit number used to represent a service provided by a healthcare provider. It is a manual that assigns five digit codes to medical services and procedures to standardize claims processing and data analysis. The coding system for physicians' services developed by the CPT Editorial Panel of the American Medical Association.

[D]

Data Content: All the data elements and code sets inherent to a transaction, and not related to the format of the transaction.

Data: This is factual information (as measurements or statistics) used as a basis for reasoning, discussion, or calculation. It additionally points to the information output by a sensing device or organ that includes both useful and irrelevant or redundant information and must be processed to be meaningful.

Database Management System (DBMS): The separation of data from the computer application that allows entry or editing of data.

DICOM (Digital Imaging and Communications in Medicine): Digital Imaging and Communications in Medicine (DICOM) is a standard to define the connectivity and communication between medical imaging devices.

Disease Management: A type of product or service now being offered by many large pharmaceutical companies to get them into broader healthcare services. Bundles use of prescription drugs with physician and allied professionals, linked to large databases created by the pharmaceutical companies, to treat people with specific diseases. The claim is that this type of service provides higher quality of care at more reasonable price than alternative, presumably more fragmented, care. The development of such products by hugely capitalized companies should be the entire indicator necessary to convince a provider of how the healthcare market is changing. Competition is coming from every direction—other providers of all types, payers, employers who are developing their own in-house service systems, the drug companies.

Document Imaging: Is a process of converting paper documents into an electronic format usually through a scanning process.

Document Management: The Document Manager allows the medical institution to store vital patient documents such as X-Ray's, Paper Reports, and Lab Reports etc.

Documentation: The process of recording information.

DOHAD: Developmental Origins of Health and Diseases

Drug Formulary: Varying lists of prescription drugs approved by a given health plan for distribution to a covered person through specific pharmacies. Health plans often restrict or limit the type and number of medicines allowed for reimbursement by limiting the drug formulary list. The list of prescription drugs for which a particular employer or State Medicaid program will pay. Formularies are either "closed," including

only certain drugs or "open," including all drugs. Both types of formularies typically impose a cost scale requiring consumers to pay more for certain brands or types of drugs. See also Formulary.

Drug Formulary Database: This EMR feature is used for electronic prescribing, electronic medical record (EMR), and computerized physician order entry (CPOE) systems to present formulary status to the provider while during the prescribing decision.

DSM: Diagnostic and Statistical Manual for Mental Diseases

[E]

EDI: Acronym for Electronic Data Interchange. Electronic communication between two parties, generally for the filing of electronic claims to payers.

EDI Translator: Used in electronic claims and medical record transmissions, this is a software tool for accepting an EDI transmission and converting the data into another format, or for converting a non-EDI data file into an EDI format for transmission. See also Electronic Data Interchange.

EHR/EMR System Designer, Developer, Manufacturer, Vendor, Supplier, Retailer, Re-seller: Any entity that is involved in the design, development, testing, manufacturing, supplying, selling including re-selling of Electronic Health Records or Electronic Medical Records Systems as a whole or part thereof.

Electronic Data Interchange (EDI): The automated exchange of data and documents in a standardized format. In health care, some common uses of this technology include claims submission and payment, eligibility, and referral authorization. This refers to the exchange of routine business transactions from one computer to another in a standard format, using standard communications protocols.

Electronic Health Records (EHR): The one or more repositories, physically or virtually integrated, of information in computer processable form, relevant to the wellness, health and healthcare of an individual, capable of being stored and communicated securely and of being accessible by multiple authorized users, represented according to a standardized or commonly agreed logical information model. Its primary purpose is the support of life-long, effective, high quality and safe integrated healthcare. [ISO 18308:2011]

Electronic Medical Records (EMR): The EMR could be considered as special case of the EHR, restricted in scope to the medical domain or at least very much medically focused [ISO/TR 20514]. The Japanese Association of Healthcare Information Systems (JAHIS) has defined a five-level hierarchy of the EMR; Departmental EMR: contains a patient's medical information entered by a single hospital department (e.g. pathology, radiology, pharmacy); Inter-departmental EMR: contains a patient's medical information from two or more hospital departments; Hospital EMR: contains a patient's clinical information from a particular hospital; Inter-hospital EMR: contains a patient's medical information from two or more hospitals; EHR: longitudinal collection of health information from all sources. [Classification of EMR systems, JAHIS, V1.1, Mar 1996]

Electronic Protected Health Information (ePHI): Electronic Protected Health Information (ePHI) is any protected health information (PHI) that is created, stored, transmitted, or received electronically. Electronic

GLOSSARY

protected health information includes any medium used to store, transmit, or receive PHI electronically. The following and any future technologies used for accessing, transmitting, or receiving PHI electronically are covered. Media containing data at rest (data storage) like personal computers with internal hard drives used at work, home, or traveling, external portable hard drives, including iPods and similar devices, magnetic tape, removable storage devices, such as USB memory sticks, CDs, DVDs, and floppy disks, PDAs and smartphones and data in transit, via wireless, Ethernet, modem, DSL, or cable network connections, Email, File transfer. (For Protected Health Information – PHI, please see below)

Encounter: A clinical encounter is defined by ASTM as "(1) an instance of direct provider/practitioner to patient interaction, regardless of the setting, between a patient and a practitioner vested with primary responsibility for diagnosing, evaluating or treating the patient's condition, or both, or providing social worker services. (2) A contact between a patient and a practitioner who has primary responsibility for assessing and treating the patient at a given contact, exercising independent judgment." Encounter serves as a focal point linking clinical, administrative and financial information. Encounters occur in many different settings -- ambulatory care, inpatient care, emergency care, home health care, field and virtual (telemedicine). [http://www.ncvhs.hhs.gov/040127p1.htm]

Episode: An episode of care consists of all clinically related services for one patient for a discrete diagnostic condition from the onset of symptoms until the treatment is complete [http://www.ncmedsoc.org/non_members/pai/PAI-FinalWorkbookforVideo.pdf] Thus, for every new problem or set of problems that a person visits his clinical care provider, it is considered a new episode. Within that episode the patient will have one or many encounters with his clinical care providers till the treatment for that episode is complete. Even before the resolution of an episode, the person may have a new episode that is considered as a distinctly separate event altogether. Thus, there may be none, one or several ongoing active episodes. All resolved episodes are considered inactive. Hence they become part of the patient's past history. A notable point here is that all chronic diseases are considered active and may never get resolved during the life-time of the person, e.g., diabetes mellitus, hypertension, etc.

EPR: Broadly defined, a personal health record is the documentation of any form of patient information–including medical history, medicines, allergies, visit history, or vaccinations–that patients themselves may view, carry, amend, annotate, or maintain. Today, when we refer to PHRs, we typically mean an online personal health record–which may variously be referred to as an ePHR, an Internet PHR, an Internet medical record, or a consumer Internet Medical Record (CIMR). Generally, such records are maintained in a secure and confidential environment, allowing only the individual, or people authorized by the individual, to access the medical information. Not all electronic PHRs are Internet PHRs. PC-based PHRs may be set up to capture medical information offline.

Evidence Based Medicine: Evidence-based medicine (EBM) is the integration of best research evidence with clinical expertise to aid in the diagnosis and management of patients.

[F]

122

Family History: A list of the patient's family medical history including the chronic medical problems of parents, siblings, grandparents, etc.

FHIR: Fast Health Interoperable Resources, the newest version from HL7 org for messaging.

Formatting and Protocol Standards: Data exchange standards which are needed between CPR systems, as well as CPT and other provider systems, to ensure uniformity in methods for data collection, data storage and data presentation. Proactive providers are current in their knowledge of these standards and work to ensure their information systems conform to the standards.

Formulary: An approved list of prescription drugs; a list of selected pharmaceuticals and their appropriate dosages felt to be the most useful and cost effective for patient care. Organizations often develop a formulary under the aegis of a pharmacy and therapeutics committee. In HMOs, physicians are often required to prescribe from the formulary. See also Drug Formulary.

[G]

Growth Chart: A feature for a Primary Care or EMR that can be used for pediatric patients. Age, height, weight, and head measurements can be entered over the patient's lifetime, and the feature creates a line graph.

[H]

Health Care Operations: Institutional activities that is necessary to maintain and monitor the operations of the institution. Examples include but are not limited to: conducting quality assessment and improvement activities; developing clinical guidelines; case management; reviewing the competence or qualifications of health care professionals; education and training of students, trainees and practitioners; fraud and abuse programs; business planning and management; and customer service. Under the HIPAA Privacy Rule, these are allowable uses and disclosures of identifiable information "without specific authorization." Research is not considered part of health care operations.

Health Care, Healthcare: Care, services, and supplies related to the health of an individual. Health care includes preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, among other services. Healthcare also includes the sale and dispensing of prescription drugs or devices.

Health Information: Information in any form (oral, written or otherwise) that relates to the past, present or future physical or mental health of an individual. That information could be created or received by a health care provider, a health plan, a public health authority, an employer, a life insurer, a school, a university or a health care clearinghouse. All health information is protected by state and federal confidentiality laws and by HIPAA privacy rules.

Health Level Seven (HL7): A data interchange protocol for health care computer applications that simplifies the ability of different vendor-supplied IS systems to interconnect. Although not a software program in itself, HL7 requires that each healthcare software vendor program HL7 interfaces for its products. The organization is one of the American National Standards Institute accredited Standard Developing Organization (SDO) - Health Level 7 domain is the standards for electronic interchange of clinical, financial and administrative info among healthcare oriented computer systems. Is a not-for-profit volunteer organization. It develops specifications, most widely used is the messaging standard that enables disparate health care applications to exchange key sets of clinical and administrative data. It promotes the use of standards within and among healthcare organizations to increase the effectiveness and efficiency of healthcare delivery. It is an international community of healthcare subject matter experts and information scientists collaborating to create standards for the exchange, management and integration of electronic healthcare information.

Health: The state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity. It is recognized, however, that health has many dimensions (anatomical, physiological, and mental) and is largely culturally defined. The relative importance of various disabilities will differ depending upon the cultural milieu and the role of the affected individual in that culture. Most attempts at measurement have been assessed in terms or morbidity and mortality.

Healthcare provider: A health care provider is an individual or an institution that provides preventive, curative, promotional or rehabilitative health care services in a systematic way to individuals, families or communities. An individual health care provider may be a health care professional, an allied health professional, a community health worker, any or other person trained and knowledgeable in medicine, nursing or other allied health professions, or public/community health workers like , ASHA, ANM, midwives, paramedical staff, OT/lab/radio-diagnostic technicians, etc. An institution will include hospitals, clinics, primary care centers and other service delivery points of health care individual clinics, polyclinics, diagnostic centers, etc., i.e., any place where a medical record is generated during a patient-care provider encounter (in conformance to CEA 2010 – please refer to Clinical Establishment item above). It must be noted that any person solely performing non-clinical work is not a care provider.

Healthcare Service Provider (HSP): see Healthcare provider

History of Present Illness (HPI): The HPI is the history of the patient's chief complaint.

Human Subject: Refers to a living subject participating in research about whom directly or indirectly identifiable health information or data are obtained or created.

Hybrid Record: Term used for when a provider uses a combination of paper and electronic medical records during the transition phase to EMR.

[I]

Independent Software Vendor (ISV): A company specializing in making or selling software products that runs on one or more computer hardware or operating system platforms.

Immunization: A complete list of all immunizations that the patient has had.

Informatics: The application of computer technology to the management of information.

Integration: Integration allows for secure communication between enterprise applications.

120

Interface: A means of communication between two computer systems, two software applications or two modules. Real time interface is a key element in healthcare information systems due to the need to access patient care information and financial information instantaneously and comprehensively. Such real time communication is the key to managing health care in a cost effective manner because it provides the necessary decision-making information for clinicians, providers, other stakeholders, etc.

International Classification of Diseases: This is the universal coding method used to document the incidence of disease, injury, mortality and illness. A diagnosis and procedure classification system designed to facilitate collection of uniform and comparable health information. The ICD-9-CM was issued in 1979. This system is used to group patients into DRGs, prepare hospital and physician billings and prepare cost reports. Classification of disease by diagnosis codified into six-digit numbers. See also coding.

International Health Terminology Standards Development Organization (IHTSDO): Denmark-based organization that maintains and licenses SNOMED codes worldwide.

Interoperability: The capability to provide successful communication between end-users across a mixed environment of different domains, networks, facilities and equipment.

ISP: Internet Service Provider

ISV (Independent Software Vendor): An independent software vendor (ISV) is a company specializing in making or selling software, designed for mass or niche markets. This typically applies for application-specific or embedded software, from other software producers.

[J]

J-Codes: A subset of the HCPCS Level II code set with a high-order value of "J" that has been used to identify certain drugs and other items.

[L]

LAN (Local Area Network): A LAN supplies networking capability to a group of computers in close proximity to each other such as in an office building, a school, or a home.

Legacy System Integration: The integration of data between a legacy system and some other software program most commonly using HL-7 standards.

Legacy Systems: Computer applications, both hardware and software, which have been inherited through previous acquisition and installation. Most often, these systems run business applications that are not integrated with each other. Newer systems which stress open design and distributed processing capacity are gradually replacing such systems.

Length of Stay (LOS): The duration of an episode of care for a covered person. The number of days an individual stays in a hospital or inpatient facility. May also be reviewed as Average Length of Stay (ALOS).

110

GLOSSARY

LEPR (Longitudinal Patient Record): Longitudinal Patient Record is an EHR that includes all healthcare information from all sources.

[M]

Management Information System (MIS): The common term for the computer hardware and software that provides the support of managing the plan.

Master Patient / Member Index: An index or file with a unique identifier for each patient or member that serves as a key to a patient's or member's health record.

Maximum Defined Data Set: All of the required data elements for a particular standard based on a specific implementation specification. An entity creating a transaction is free to include whatever data any receiver might want or need. The recipient is free to ignore any portion of the data that is not needed to conduct their part of the associated business transaction, unless the inessential data is needed for coordination of benefits.

MCI: Medical Council of India

Medical Code Sets: Codes that characterize a medical condition or treatment. These code sets are usually maintained by professional societies and public health organizations. Compare to administrative code sets.

Medical Informatics: Medical informatics is the systematic study, or science, of the identification, collection, storage, communication, retrieval, and analysis of data about medical care services to improve decisions made by physicians and managers of health care organizations. Medical informatics will be as important to physicians and medical managers as the rules of financial accounting are to auditors.

Medical Management Information System (MMIS): A data system that allows payers and purchasers to track health care expenditure and utilization patterns. It may also be referred to as Health Information System (HIS), Health Information Management (HIM) or Information System (IS). See also Electronic Medical Record (EMR).

Metadata and Date Standard (MDDS) – A set of data elements and their specification for use in certain domain, such as health, e-governance.

MIMS: Monthly Index of Medical Specialties

Minimum Data Set: The minimum set of data elements that must be captured, stored, made available for retrieval, presentation, relay and sharing by an EHR system. It comprises of all of the essential data elements required for implementation. An entity creating a transaction must include the mandatory data elements at all times and is free to exclude optional data elements. The entity is free to additionally include whatever other data elements that any receiver might want or need. The recipient is free to ignore any portion of the data that is not mandatory and is further free to ignore any other portion of the data that is not needed to conduct their part of the associated transaction, unless required by sender, intermediaries or receiver. This minimum data set represents the most common data, and system designers are at liberty to add to it as they deem necessary to enrich or enhance their EHR systems.

118

Modifier: Additional character of a code added to an existing code that is used to help in extending or localization of the existing code.

[N]

NANDA: North American Nursing Diagnosis Association

National Council for Prescription Drug Programs: An ANSI-accredited group that maintains a number of standard formats for use by the retail pharmacy industry.

NEMA: The National Electrical Manufacturers Association (NEMA) is the association of electrical equipment and medical imaging manufacturers, founded in 1926 and headquartered in Rosslyn, Virginia.

Non-Participating Physician (or Provider): A provider, doctor or hospital that does not sign a contract to participate in a health plan, usually which requires reduced rates from the provider. In the Medicare Program, this refers to providers who are therefore not obligated to accept assignment on all Medicare claims. In commercial plans, non-participating providers are also called out of network providers or out of plan providers. If a beneficiary receives service from an out of network provider, the health plan (other than Medicare) will pay for the service at a reduced rate or will not pay at all.

[O]

Open Access: A term describing a member's ability to self-refer for specialty care. Open access arrangements allow a member to see a participating provider without a referral from another doctor. Health plan members' abilities, rights or invitation to self refer for specialty care. Also called Open Panel.

openEHR: openEHR is an open standard specification in health informatics that describes the management and storage, retrieval and exchange of health data in electronic health records (EHRs). In openEHR, all health data for a person is stored in a "one lifetime", vendor-independent, person-centered EHR. Maintained by the openEHR Foundation, these are based on a combination of 15 years of European and Australian research and development into EHRs and new paradigms, including what has become known as the archetype methodology for specification of content and include information and service models for the EHR, demographics, clinical workflow and archetypes. They are designed to be the basis of a medico-legally sound, distributed, versioned EHR infrastructure.

OR: Operating Room – synonymous to OT as below

OT: Operation Theatre

OTC: Over the counter (drugs). Refers to those drugs that are available off the shelf without any prescription or advise from a registered medical practitioner

Outcome: A clinical outcome is the "change in the health of an individual, group of people or population which is attributable to an intervention or series of interventions". (Taken from: Frommer, Michael; Rubin, George; Lyle, David (1992)."The NSW Health Outcomes program". New South Wales Public Health Bulletin 3: 135. doi:10.1071/NB92067)

GLOSSARY

Outpatient Care: Care given a person who is not bedridden. It is also called ambulatory care. Many surgeries and treatments are now provided on an outpatient basis, while previously they had been considered reason for inpatient hospitalization. Some say this is the fastest growing segment of healthcare

[P]

Participating Physician: A primary care physician in practice in the payer's managed care service area who has entered into a contract.

Past History: A list of a patient's past health problems, surgeries and specialists.

Patient Demographics: All patient's pertinent information such as first and last name, SSN, DOB, insurance, etc.

Patient Portal: A secure web-based system that allows a patient to register for an appointment, schedule an appointment, request prescription refills, send and receive secure patient-physician messages, view lab results, pay their bills electronically, access physician directories.

Patient: A person who is under medical care or treatment

PC Based: A program designed to run on an individual PC. This typically means data is not shared in real time among other PCs (users).

PCP: Primary care physician who often acts as the primary gatekeeper in health plans. That is, often the PCP must approval referrals to specialists. Particularly in HMOs and some PPOs, all members must choose or are assigned a PCP.

PHR: A personal health record or PHR is typically a health record that is initiated and maintained by an individual. An ideal PHR would provide a complete and accurate summary of the health and medical history of an individual by gathering data from many sources and making this information accessible online.

Picture Archive Communication System (PACS): Used by radiology and diagnostic imaging organizations to electronically manage information and images

Practice Parameters, Practice Guidelines: Systematically developed statements to standardize care and to assist in practitioner and patient decisions about the appropriate health care for specific circumstances. Practice guidelines are usually developed through a process that combines scientific evidence of effectiveness with expert opinion. Practice guidelines are also referred to as clinical criteria, protocols, algorithms, review criteria, and guidelines. The American Medical Association defines practice parameters as strategies for patient management, developed to assist physicians in clinical decision-making. Practice parameters may also be referred to as practice options, practice guidelines, practice policies, or practice standards.

Prescription Drug: Drug that the law says can only be obtained by prescription.

116

GLOSSARY

Primary Care Physician: A "generalist" such as a family practitioner, pediatrician, internist, or obstetrician. In a managed care organization, a primary care physician is accountable for the total health services of enrollees including referrals, procedures and hospitalization. Also see Primary Care Provider.

Primary Care Provider: The provider that serves as the initial interface between the member and the medical care system. The PCP is usually a physician, selected by the member upon enrollment, who is trained in one of the primary care specialties who treats and is responsible for coordinating the treatment of members assigned to his/her plan.

Primary Care: Basic or general health care usually rendered by general practitioners, family practitioners, internists, obstetricians and pediatricians who are often referred to as primary care practitioners or PCPs. Professional and related services administered by an internist, family practitioner, obstetrician-gynecologist or pediatrician in an ambulatory setting, with referral to secondary care specialists, as necessary.

Principal Diagnosis: The medical condition that is ultimately determined to have caused a patient's admission to the hospital. The principal diagnosis is used to assign every patient to a diagnosis related group. This diagnosis may differ from the admitting and major diagnoses.

Privacy Standards: The Privacy standards restrict the use & disclosure of individually identifiable health information. Privacy standard applies to all protected health information may it is in physical or electronic form.

Privacy: Privacy means an individual's interest in limiting who has access to personal health care information. Specific patient authorization is required for use and disclosure of clinical notes. As per Fernando & Dawson, 2009, privacy is control of access to private information avoiding certain kinds of embarrassment and can be shared or not shared with others; Only authorized (by the patient) people can view the recorded data or part thereof

Progress Note: The documentation of a patient visit or encounter including all or part of the SOAP format.

Protected health information (PHI): Any individually identifiable information whether oral or recorded in any form or medium that is created, or received by a health care provider, health plan or health care Healthcare provider and relates to past, present, or future physical or mental health conditions of an individual; the provision of health care to the individual; or past, present, or future payment for health care to an individual.

[R]

Real Time: The instantaneous sharing of data among a user group. It is common to a client/server database configuration.

Reference Model (RM):

Referral: Some insurance companies require that on specific plans a referral must be obtained for certain procedures or visits to specialists. The referral is acquired by the primary care physician (PCP) by contacting

45

the insurance company by phone or mail. This is a request for the service. The referral consists of an authorization code, a number of visits allowed (if applicable) and an expiration date.

Referring Provider: is the provider that referred the patient to a specialist or for a specific procedure.

Regenstrief: The Regenstrief Institute is an international non-profit medical research organization associated with Indiana University. It produces and maintains LOINC codes.

Relational Database: A database program that stores data in a manner similar to Excel, with the difference being the data elements are related (linked) to each other.

Remote Access: Data travels through a private, protected passage via the Internet, allowing healthcare providers to access from home or another practice location and allows EMR vendor to perform system maintenance off-site

Rendering/Performing Provider: The provider actually treating the patient.

Roles and Access Levels: The role and access level of the user needs to be determined and set by the system administrator. The role determines the access level. While roles may be such as system administrator, medical doctor, registered nurse, medical student, medical assistant, nurse assistant, ancillary nurse, health worker, Anganwadi worker (grass-root health worker), etc., the access levels may include viewing only, viewing/adding/editing only, viewing/adding/editing/deleting, all allowed etc. These need to be set out clearly in the SOP of the facility.

ROS (Review of Systems): A series of questions related to the system(s) that the patient is having complaints about (i.e. respiratory for cold symptoms).

RxNorm: RxNorm is the name of a US-specific terminology in medicine that contains all medications available on US market; it provides normalized names for clinical drugs and links its names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software.

[S]

Secondary Care: Services provided by medical specialists who generally do not have first contact with patients (e.g., cardiologist, urologists, dermatologists). In the U.S., however, there has been a trend toward self-referral by patients for these services, rather than referral by primary care providers. This is quite different from the practice in England, for example, where all patients must first seek care from primary care providers and are then referred to secondary and/or tertiary providers, as needed.

Security Standards: The Security Standards require measures to protect the confidentiality, integrity and availability of e-PHI while it's being stored & exchanged. The security standard applies to all electronic PHI.

Security: This refers to the methods and techniques adopted to protect privacy and are a defense mechanism from any attack (Hong et al., 2004)

114

SNOMED: Systemized Nomenclature of Medicine Clinical Terms is the universal health care terminology. It is comprehensive and covers procedures, diseases, and clinical data. SNOMED CT helps to structure and computerize the medical record. It allows for a consistent way of indexing, storing, retrieving and aggregating clinical data across sites of care (i.e. hospitals, doctors offices) and specialties. By standardizing the terminology, the variability in the way data is captured, encoded and used for clinical care of patients and research is reduced. Allows for more accurate reporting of data. It is currently available in English, Spanish and German.

Social History: A description of a patient's social habits and history including marital status, alcohol and drug use and exercise habits.

Solo Practice, Solo Practitioner: A physician who practices alone or with others but does not pool income or expenses. This form of practice is becoming increasingly less common as physicians band together for contracting, overhead costs and risk sharing.

SOP: Standard operating procedures or protocols

SQL: Structured Query Language – is a computer language aimed to store, manipulate and retrieve data stored in relational databases.

SDO: Standards Development Organization – an organization responsible for development and maintenance of a standard or several, usually run on a not-for-profit basis.

Subjective: Section in a progress note where a patient's account of their current problem is documented. Consists of chief complaint, HPI and ROS.

Sx: Abbreviation for symptoms

[T]

T1, T3 line: A high-speed internet connection provided via telephone lines often used by businesses needing internet connection speeds greater than DSL/Cable.

Therapeutic Alternatives: Strong Drug products that provide the same pharmacological or chemical effect in equivalent doses. Also see Drug Formulary.

TPA: Third Party Administrator

Treatment Episode: The period of treatment between admission and discharge from a modality, e.g., inpatient, residential, partial hospitalization, and outpatient, or the period of time between the first procedure and last procedure on an outpatient basis for a given diagnosis. Many healthcare statistics and profiles use this unit as a base for comparisons.

Treatment: The provision of health care by one or more health care providers. Treatment includes any consultation, referral or other exchanges of information to manage a patient's care.

GLOSSARY

[V]

Vital Statistics: Statistics relating to births (natality), deaths (mortality), marriages, health, and disease (morbidity). Vital statistics for the United States are published by the National Center for Health Statistics. Vital statistics can be obtained from CDC, state health departments, county health departments and other agencies. An individual patient's vital statistics in a health care setting may also refer simply to blood pressure, temperature, height and weight, etc.

VPN: Virtual Private Network – A VPN "tunnel" is a secure connection, typically firewall to firewall that provides for remote access to your data server.

[W]

WHO: The World Health Organization is a specialized agency of the United Nations that is concerned with international public health.

[X]

XML (Extensible Markup Language): Used for defining data elements on a Web page and communication between two business systems. Example: Standard messaging system for and EMR to integrate with another software such as a practice management or drug formulary database.

112

CONTACT INFORMATION

Contact Information

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Implementation specific queries may be referred to:
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VC&BA, Centre for Development of Advanced Computing (C-DAC)
Savitribai Phule Pune University Campus
Ganeshkhind Road
Pune – 411007
Email: nrc-help@cdac.in
http://www.snomedctnrc.in

Subject: **RE: Minutes of the first Meeting of the Electronic Health Record (EHR) review committee held on 26th August 2015**
Date: 09/09/15 05:31 PM
From: "NARWAL, Rajesh" <narwalr@who.int>
To: Jitendra Arora <dir.ehealth@gmail.com>
Cc: amit.k89@gov.in <amit.k89@gov.in>,
bedi11@yahoo.com <bedi11@yahoo.com>,
SBB <sbbhattacharyya@gmail.com>,
"GODARA, Balwant" <godarab@who.int>

Dear Mr Arora,

Thank you for inviting WHO to this very important first meeting of the EHR review Committee. We fully support the MoHFW's move to review the existing standards and resolving the inconsistencies with MDDS. While developing the new HER standards, another principle to be kept in mind is that the new standards should be simple and intuitive enough to be adopted by smaller hospitals and clinics also, rather than solely tailored to the capabilities of Tertiary Care or Corporate hospitals. Infact different levels of complexity could be inbuilt so that end users could choose specific levels they wish to use, according to their needs and proficiency (may not be in totality).

On a separate note, given the recent change in leadership, it may be a good idea for MoHFW to steer and follow up on the work of the EHR review committee. We would be glad to facilitate if any technical or operational inputs are required from our end.

Thank you and regards

Rajesh

Dr Rajesh Narwal, MD, MPH

Technical Officer- Health Systems Stewardship and Regulations

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Subject: **Minutes of the first Meeting of the Electronic Health Record (EHR) review committee held on 26th August 2015**
Date: 09/08/15 11:44 AM
From: Amit Kumar <amit.k89@gov.in>
To: Jitendra Arora <dir.ehealth@gmail.com>, sunil.bhushan@gov.in, kbhatia@gov.in, supten@nihfw.org, supten@gmail.com, gaurs@cdac.in, bedi11@yahoo.com, drkaranvir_s@apollohospitals.com, sudhir.saxena@nisg.org, narwalr@who.int, shobha.mishra@ficci.com, dr.amitmishra@gmail.com
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Minutes of the first Meeting of the Electronic Hea... (929kB)

File No. Q-11011/3/2015-eGov

Government of India

Ministry of Health & Family Welfare

(eGovernance Division)

***

Nirman Bhawan, New Delhi

Dated 7th September, 2015

OFFICE MEMORANDUM

Subject: Minutes of the first Meeting of the Electronic Health Record (EHR) review committee held on 26th August 2015

The undersigned is directed to circulate the minutes of the first meeting of EHR Review Committee held on 26th August, 2015 in MoHFW under the Chairmanship of Shri N B Dhal, JS (eGov).

To

1. Shri Jitendra Arora - Director, eGov
2. Shri Sunil Kumar - STD, NIC, MoHFW
3. Ms Kavita Bhatia - Addl Director, DeitY
4. Prof S N Sarbadhikari - Project Director, CHI of NHP
5. Shri B S Bedi - Advsior, C-DAC
6. Shri Gaur Sunder - PTO, C-DAC Pune
7. Dr Rajesh Narwal - Technical Officer Health System
8. Shri Sudhir Saxena - VP NISG
9. Dr S B Bhattacharyya - Head Health Informatics, TCS

10. Dr Karanvir Singh - CMIO, Apollo Hospitals
11. Ms Shobha Mishra Ghosh - Senior Director, FICCI

Copy To:

1. PPS to AS (KBA)
2. PPS to JS (eGov)

Regards

Amit Kumar

Assistant Director (eGovernance)

Ministry of Health & Family Welfare

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08 SEP 2015

स्पीड पोस्ट द्वारा
BY SPEED POST

O/c

108

File No. Q-11011/3/2015-eGov
Government of India
Ministry of Health & Family Welfare
(eGovernance Division)
***

Nirman Bhawan, New Delhi
Dated 7th September, 2015

OFFICE MEMORANDUM

Subject: **Minutes of the first Meeting of the Electronic Health Record (EHR) review committee held on 26th August 2015**

The undersigned is directed to circulate the minutes of the first meeting of EHR Review Committee held on 26th August, 2015 in MoHFW under the Chairmanship of Shri N B Dhal, JS (eGov).

(Sunita Dhaundiyal)
Under Secretary to the GoI
Telephone: 23061843

To

1. Shri Jitendra Arora - Director, eGov
2. Shri Sunil Kumar - STD, NIC, MoHFW — 8-9-15
3. Ms Kavita Bhatia - Addl Director, DeitY FTS 72354
4. Prof S N Sarbadhikari - Project Director, CHI of NHP
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6. Shri Gaur Sunder - PTO, C-DAC Pune
7. Dr Rajesh Narwal - Technical Officer Health System
8. Shri Sudhir Saxena - VP NISG
9. Dr S B Bhattacharyya - Head Health Informatics, TCS
10. Dr Karanvir Singh - CMIO, Apollo Hospitals
11. Ms Shobha Mishra Ghosh - Senior Director, FICCI 72358

Pls issue R&I
By speed post
8-9-15

Copy To:

1. PPS to AS (KBA) 8/9/15
2. PPS to JS (eGov)

Department of Health & Family Welfare

e-Governance Division

****

Subject: Minutes of the First Meeting of the Electronic Health Record (EHR) Review Committee held on 26th August, 2015

The first meeting of 'EHR Standards Review Committee' was held on 26th August, 2015 at 4:00 P.M. in the Room No.406, A –Wing, Nirman Bhawan, Ministry of Health & Family Welfare under the Chairmanship of Shri N B Dhal, JS(eGov). Shri K B Agarwal, AS, MoHFW also joined the meeting. Representatives from WHO, FICCI and NISG attended the meeting as special invitees. The list of participants is placed at **Annexure - A**.

2. Shri N.B. Dhal, JS(eGov) welcomed the participants and briefed them about the overall objective/purpose of EHR Standards which had been notified by MoHFW in September 2013 after detailed deliberations with various stakeholder groups. He highlighted that EHR Standards being a living document needed to be reviewed/updated periodically – for ensuring compliance with the prevailing global standards, practices etc. Accordingly, it was decided with approval of the competent authority to constitute a committee to review the EHR standards- 'EHR Review Committee' (copy of order placed at **Annexure B**). The representatives from FICCI (which coordinated the task for notification of EHR Standards in 2013), WHO and NISG were invited to attend the first meeting of EHR Standards Review Committee.

3. JS(eGov) mentioned about approach that may be followed to obtain comments from stakeholders regarding revision of the EHR Standards document and sought views of the Review Committee members on whether the Ministry should seek suggestions from various stakeholders on the already notified standards through Ministry's website, MyGov platform etc. and entrust institution/organisation like Centre for Health Informatics (CHI) -NIHFW or C-DAC, Pune to carry out the coordination role. JS(eGov) thereafter requested Shri B.S. Bedi, Advisor, CDAC to brief the participants further on the subject.

4. Shri B.S. Bedi provided a brief background to the detailed task carried out MoHFW and its EHR Standards Committee related to adoption and notification of standards. He emphasized upon the need for review / revision of the standards as it has already been two years since the standards were notified.

5. Dr. S.B. Bhattacharya, Head Health Informatics, TCS informed the participants that some suggestions had already been received by the members of EHR Standards Committee and it would be appropriate that those suggestions be examined by the Review Committee members. He proposed that a sub-group – comprising self, Shri Gaur Sunder (CDAC-Pune) & Shri S.N. Sarbadhikari (Project Director, CHI) – may be formed under the Review Committee and entrusted with the task of preparing a revised draft of the Standards. And once a revised document is drafted on the Standards, it may be put in public domain for seeking suggestions/feedback. Shri Gaur Sunder mentioned that iNRC SNOMED-CT had also received few suggestions on the EHR Standards document and the same could be examined.

6. Shri Bedi supported to the above mentioned suggestions on approach to be taken for review/revision of the Standards. He pointed out that the Review Committee also needed to address the issue of inconsistencies between the draft Metadata & Data Standards (MDDS) prepared by the MDDS Committee for Health Domain and the notified EHR Standards.

7. Shri Sunil Bhushan, Senior Technical Director, NIC and a member of MDDS Committee mentioned that most of the issues pertaining to inconsistencies between MDDS draft and EHR Standards had been jointly deliberated and resolved. However, there are still some instances of inconsistency, which could be resolved during the course of review/revision of EHR Standards.

8. Shri Arvind Sivaramakrishnan, CIO, Apollo Hospitals also stated that the inconsistencies between the draft MDDS document & EHR standards document should be resolved and appropriately incorporated in the revised EHR Standards.

9. Ms. Kavita Bhatia, Scientist-E, eGov, DeitY made a submission to the Review Committee that DeitY had already published MDDS for Demographics in 2011 and the same had already been

105

adopted by various Ministries. Therefore, it is requested that the Review Committee should adopt the Demographics MDDS while revising the EHR Standards to ensure interoperability and coherence with other eGovernance projects.

10. Thereafter, JS(eGov) apprised AS(eGov) and other participants about 'India Health Information Network (IHIN)' - a network consisting of broad spectrum of participants from different quarters of healthcare sector- constituted by MoHFW in January 2015 for eHealth knowledge/experience sharing, to act as think-tank for policy level issues etc. Currently, FICCI is facilitating and coordinating the activities of IHIN. IHIN has formulated different working groups including one on EHR Standards and the suggestions made by this working group may be shared with the Review Committee.

11. JS(eGov) further mentioned that DeitY had raised concerns about SNOMED CT not being open standards. This issue was discussed in detail with iNRC team and the members of EHR Standards Committee. Accordingly a reply was sent by Secretary(HFW) to Secretary(DeitY) highlighting key features – wide scale use of SNOMED CT in around 85 countries, its comprehensiveness etc.- and that DeitY was involved in the decision taken to obtain license of IHTSDO. He then requested the participants to share their views on this issue.

12. Ms. Kavita Bhatia stated that DeitY had some reservations whether SNOMED-CT meets the requirements of the policy on Open Standards, it involves payment of royalty. Therefore DeitY sought clarifications regarding structure of IHTSDO, role/influence of private sector organizations in IHTSDO, any migration issues once new standards come up, efforts being put in for awareness creation / promotion of SNOMED-CT etc.

13. The responses of EHR Review Committee Members regarding the concern raised and clarifications sought by DeitY representative on SNOMED CT are summarized below:

- It is a clinical terminology/vocabulary/ coding system, **not** software. It has functions in medical domain like ASCII / UNICODE has in computers.

- It is the only clinical terminology code system that has successfully been able to meet requirements of the clinicians for a proper code system to capture clinical observations into the system without having to resort to free text. It is a very comprehensive code system and links/maps with all other major coding system in healthcare- WHO's ICD-10, LOINC codes etc. and almost all other standards in health informatics like; DICOM, HL7, EHRCom, etc. support using SNOMED CT codes. It can take care of semantic interoperability.
- SNOMED CT can be used in any Hospital Information System and EHR software and as per the decision taken by MoHFW, it is available free of cost/royalty for use in India. It doesn't limit or bound any user to use it in its entirety. SNOMED-CT is structured in such a manner that it supports open framework and there would not be any migration issue in future.
- Regarding being open vs. subscription, it is mentioned that IHTSDO is akin to any other Standard Development Organization (SDO). Most SDOs also charge a fee for using, referring, distribution of standards among members and non-members and India pays a membership fee to ITU, WHO etc. for using their standards. IHTSDO's governance structure is similar in nature to ITU, ISO, IEEE etc. and is a non-profit organization with about 30 nations as members; private vendor organizations don't form part of IHTSDO.
- India being a country member of IHTSDO could be able to strategically participate in the overall process/structure of standards formulation/revision keeping its local requirements in view. India could also promote inclusion of AYUSH in the clinical terminology standards/codes, in future. Over 85 countries are using SNOMED CT including in Asia-pacific region and its coverage is continuously increasing.

✓ 14. Based on detailed discussions, the following decisions were taken in the meeting:

- Sub-committee comprising Shri B.S. Bedi, Shri Bhattacharya & Shri Gaur Sunder will prepare a draft version of the revised EHR Standards and the same would be presented before the Review Committee in a month's time.

103

- All the inconsistencies highlighted between EHR Standards and draft MDDS should be resolved and appropriately incorporated in the revision. For clinical terms the EHR Standards should supersede the draft MDDS and convergence should be ensured with the Demographics MDDS already notified in 2011 by DeitY.
- The Review Committee should meet after one month.

The meeting ended with vote of thanks to the chair and the participants

Annexure – A

List of Participants

1. Shri Jitendra Arora - Director, eGov
2. Shri Sunil Kumar - STD, NIC, MoHFW
3. Ms Kavita Bhatia - Addl Director, DeitY
4. Prof S N Sarbadhikari - Project Director, CHI of NHP
5. Shri B S Bedi - Advsior, C-DAC
6. Shri Arvind Sivaramakrishnan - Group CIO, Apollo Hospitals
7. Shri Gaur Sunder - PTO, C-DAC Pune
8. Dr Rajesh Narwal - Technical Officer Health System
9. Shri Sudhir Saxena - VP NISG
10. Dr S B Bhattacharyya - Head Health Informatics, TCS
11. Dr Karanvir Singh - CMIO, Apollo Hospitals
12. Ms Shobha Mishra Ghosh - Senior Director, FICCI
13. Shri Chandrasen - PL (ePMU)
14. Shri Nikhil - Consultant eGov
15. Shri Bhanu Prakash - Consultant ePMU

Department of Health & Family Welfare

e-Governance Division

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- All the inconsistencies highlighted between EHR Standards and draft MDDS should be resolved and appropriately incorporated in the revision. For clinical terms the EHR Standards should supersede the draft MDDS and convergence should be ensured with the Demographics MDDS already notified in 2011 by DeitY.
- It was decided to record the responses provided by the members of the EHR Review Committee against reservation expressed by DeitY on SNOMED-CT for circulation to all stakeholders.
- The Review Committee should meet next after one month.

The meeting ended with vote of thanks to the chair and the participants.

96

Annexure – A

List of Participants

1. Ms Kavita Bhatia - Addl Director, DeitY
2. Shri Jitendra Arora - Director, eGov
3. Shri Sunil Kumar - STD, NIC, MoHFW
4. Prof S N Sarbadhikari - Project Director, CHI of NHP
5. Shri B S Bedi - Advsior, C-DAC
6. Shri Arvind Sivaramakrishnan - Group CIO, Apollo Hospitals
7. Shri Gaur Sunder - PTO, C-DAC Pune
8. Dr Rajesh Narwal - Technical Officer Health System
9. Shri Sudhir Saxena - VP NISG
10. Dr S B Bhattacharyya - Head Health Informatics, TCS
11. Dr Karanvir Singh - CMIO, Apollo Hospitals
12. Ms Shobha Mishra Ghosh - Senior Director, FICCI
13. Shri Chandrasen - PL (ePMU)
14. Shri Nikhil - Consultant eGov
15. Shri Bhanu Prakash - Consultant ePMU

Ministry of Health & Family Welfare
e-Governance Division
****

Subject: Meeting of EHR Review Committee.
Venue: 406-A Wing. Time: 04.00 PM. Date: 26th August, 2015.

S. No.	Name	Designation	Official Address	e-mail ids	Mobile Number	Sign.
1.	Dr Rajesh Narwal	Technical Officer Health Systems	WHO-India	narwalr@who.int.	9871968672	
2.	S. SAXENA	VP	NISG	sudhir.saxena@nisg.org	9818027841	
3.	Dr S.B. Bhattacharyya	Head-Health Informatics	TCS / A.No. 776, Sector 15, Faridabad	sbhattacharyya@gmail.com (personal)	9810595261	
4.	Dr Karanvir Singh	CMIO Apollo Hospital	Apollo Hosp., Delhi	karanvir.singh@gmail.com	9810098988	
5.	JITENDRA ARORA	Director	Director		9868405368	
6.	Prof. S.N. SARBADHIKARI	Project Director CHI of NHP	NIHFW, Munirka New Delhi-67	SUPTEN@GMAIL.com	9717669574	
7.	Kavita Bhatia	Add. Director	Dept. of Electronics & IT, GoI	kbhatia@gov.in	24364729	
8.	Sunil Kumar	Senior Technical Director	NIC	sunil.bhushan@nic.in	9810901302	

S. No.	Name	Designation	Official Address	e-mail ids	Mobile Number	Sign.
9.	Gaur Sundar	Principal Tech officer	C-DAC, Pune	gaurs@cdac.in	9422512661	Gaur
10.	B.S.BEDI	Adviser	CDAC	bsbedi11@gmail.com	9868243335	
11.	Shobha Mishra Ghosh	Sr. DIRECTOR	FICCI	shobha.mishra@ficci.com	9910466116	
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13.						
14.						
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17.						
18.						
19.						

Annexure - B

No.Q-11011/3/2015-eGov
Department of Health and Family Welfare
e-Governance Section
****

Nirman Bhawan, New Delhi
Date: 05 .8.2015

ORDER

Ministry of Health and Family Welfare notified the Electronic Health Records (EHR) Standards in September, 2013 to encourage standardisation, integration and electronic information exchange amongst the various healthcare providers.

2. Subsequently, India became a member of International Health Terminology Standards Development Organisation (IHTSDO), Denmark with effective from 01.04.2014 which owns and administers the rights to SNOMED CT. All the vendors and Healthcare professionals of India can use SNOMED CT for Health IT applications to be used in India without paying any licence fee.

3. Since EHR is a living document and should be reviewed/updated periodically for ensuring compliance with prevailing global standards, devices and equipments, it has been decided with the approval of the competent authority to constitute a Committee to review the EHR Standards notified by this Ministry in 2013. The composition of the EHR Committee is as under:

(i)	Shri N.B. Dhal, JS(eGov), DoHFW	Chairman
(ii)	Dr. Supten Sarbadhikari, Project Director (NHP), NIHFW	Member
(iii)	Dr. S.B. Bhattacharya, Head, Health Informatics, TCS	Member
(iv)	Dr. B.S. Bedi, Advisor, C-DAC, Pune	Member
(v)	Shri Gaur Sunder, C-DAC, Pune	Member
(vi)	Shri Sunil Kumar Bhushan, NIC, D/o HFW	Member
(vii)	Dr. Karanvir Singh, CIO, Apollo Hospitals	Member
(viii)	Representative of DeitY	Member
(ix)	Shri Jitendra Arora, Director, D/o HFW	Convener

4. **Payment:** All non-official members of the Sub Groups, who are outstation will be eligible for reimbursement of air travel by the economy class/shortest direct route. All non-official members will be eligible for reimbursement @Rs.1500/- per diem as sitting fee for attending the Committee meetings. Outstation non-official members will also be entitled for reimbursement of hotel accommodation expenses as per actual subject to a ceiling of Rs.6500/-. TA/DA of official members of the Sub-Groups for attending the meetings shall be met from the same source from which their salary is drawn.

JArora

(Jitendra Arora)
Director
Tel.No.23062317

To:

The Chairman and all the Members of the EHR Review Committee

Copy to:

Secretary, Department of Electronics and Information Technology(DeitY), Electronics NIketan, 6 CGO Complex, Lodhi Road, New Delhi-03. It is requested that an officer of Director level may kindly be nominated for the EHR Review Committee.

Copy for kind information to: PPS to AS&DG/PPS to JS(eGov)

91

No.3(37)/2014-EG-II
Ministry of Communication & Information Technology
Department of Electronics & Information Technology
Electronics Niketan, 6-CGO Complex,
Lodhi Road, New Delhi-110003

Dated: 24.08.2015

Subject: **Meeting of Electronic Health Record (EHR) Review Committee on 26th August, 2015 at 04:00 PM in Nirman Bhawan, New Delhi- nomination reg.**

Kindly refer to your communication No. Q-11011/3/2015-eGov dated 18.08.2015 on the above mentioned subject. The undersigned is directed to inform that the following officer has been nominated from Department of Electronics & Information Technology (DeitY) for the above mentioned committee:

210927
तिथि/Date 1/9/15
Ministry of Health

Ms. Kavita Bhatia
Scientist 'E'
e-Governance Group
Department of Electronics & Information Technology
Electronics Niketan, 6-CGO Complex,
Lodhi Road, New Delhi-110003
Tel: 011-24364729
e-mail: kbhatia@gov.in

A.D (e-Governance)

K.Bidani
(Krishana Bidani)
Deputy Director
Ph. 24301393

To

Shri Amit Kumar
Assistant Director (eGovernance)
Ministry of Health & Family Welfare
Department of Health & Family Welfare
Room No. 425C, Nirman Bhawan
New Delhi-110011

Copy for information to:

Smt. Kavita Bhatia, Scientist 'E', EG Group, DeitY

EHR Standards for India

This document outlines a brief of the changes/revisions in the notified EHR Standards, as discussed in IHIN EHR Working Group meeting[1]. This brief has been prepared for facilitating discussion to be held during meeting of EHR Standards Review Committee scheduled to be held on 26 August 2015.

- **Categories of adoption of standards**

	As per EHR Standards notified in August 2013	**Revisions discussed by IHIN Working Group on EHR**
Vocabulary Standards	Notified standards: a) Logical Observation Identifiers Names and Codes (LOINC) b) International Classification of Diseases (ICD10) c) Systematized Nomenclature of Medicine--Clinical Terms (SNOMED-CT) d) Current Procedural Terminology, 4th Edition (CPT 4) e) ATC – Anatomic Therapeutic Chemical Classification of Drugs	Notified standards: a) Systematized Nomenclature of Medicine--Clinical Terms (SNOMED-CT) b) International Classification of Diseases (ICD10) c) Logical Observation Identifiers Names and Codes (LOINC®) ~~d) Current Procedural Terminology, 4th Edition (CPT 4)~~ e) ~~ATC – Anatomic Therapeutic Chemical Classification of Drugs~~
Content Exchange Standards	a) Health Level Seven (HL7) Clinical Document Architecture b) Continuity of Care Record (CCR) c) Digital Imaging and Communications in Medicine (DICOM) d) HL7 2.5.1	a) Health Level Seven (HL7) Clinical Document Architecture b) Continuity of Care Record (CCR) c) Digital Imaging and Communications in Medicine (DICOM) d) HL7 Messaging standards like 2.5.1, V3.0 and FHIR e) HL7 Reference Information Model

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[1] Minutes circulated by FICCI

- **Health care IT Standards**

Name	Class	Comments	**Revisions discussed by IHIN Working Group on EHR**
Phase 1			
UHID	Unique Health Identifier – to act as Patient Identifier	UID as a unique (primary or secondary) patient identifier. The UID should be used to identify a particular patient across all organizations (and their EMR systems); Aadhar number is recommended for use in EMR as either the primary or secondary, where the primary is an internal unique health identifier used by the healthcare provider organisation.	
CCD (HL7/ASTM)	Clinical Data for Inter Department documents (the CDA CCD)	Likely to be used for exchanging the clinical documentation between two EHR solutions both within an organisation and outside	
~~ATC Pharmacologic-Therapeutic Classification Indian Drugs — MIMS/CIMS from CMPmedica~~	~~Medicines~~	~~Needs to be researched as there is no universal drug reference database. The WHO Drug Dictionary ATC – anatomic therapeutic classification – may be a good choice to begin with~~	To be dropped
LOINC	Clinical Laboratory Observations	Published and maintained by the Regenstrief Institute, USA, this is a universally accepted code for laboratory observations	
HL7 V2.x	Messaging	V2.3 or above	
HL7 V3.0 RIM	Reference Information Model	Intermediate recommendation; to be replaced with HL7 FHIR when it is accepted by BIS/HL7-India	
DICOM PS3.0	Medical	Revision 2004	
ISO 18308	Reference EHR	The latest version	
CEN / TC 251 EN	Reference	The latest version	

88

Name	Class	Comments	**Revisions discussed by IHIN Working Group on EHR**
SNOMED-CT	Clinical Terminology	Provide comprehensive clinical granularity, used to capture problem list, allergies, diagnosis, procedures etc. – will immensely aid in clinical analytics, clinical decision support systems, automated clinical care pathway management systems, support evidence based practice, etc.	
WHO ICD 10	Disease classification	WHO is actively working with IHTSDO to converge SNOMED-CT with ICD	
~~WHO PCS~~	~~Procedure coding system~~		To be dropped
~~WHO ICF~~	~~International classification~~		To be dropped
Phase 2			
~~DSM~~	~~Psychiatric conditions~~	~~Diagnostic & statistical manual of mental disorders~~	To be dropped
~~NIC/NOC/NANDA~~	~~Nursing interventions classification~~	~~This is optional~~	To be dropped
~~CDT 2, US~~	~~Dental Procedures~~	~~This is optional~~	To be dropped
ICTM	International Classification of Traditional Medicine	Ayurveda, Yoga, Unani, Siddha, Homeopathy systems of medicine as distinct from the allopathic (Western) system of medicine	

- **Standards (the latest version) that are to be additionally incorporated**

S. No.	Doc No	Description	**Revisions discussed by IHIN Working Group on EHR**
1	ISO 21090: 2011	Harmonized data types for information interchange	
2	ISO 12967: 2009	Health Informatics Service Architecture (Parts 1 - 3)	
~~3~~	~~ISO TS 22220: 2011~~	~~Identification of subjects of health care~~	To be dropped
4	ISO TS 27527: 2010	Provider identification	
5	ISO TS 14265	Classification of purposes for processing personal health information	
~~6~~	~~ISO 13940~~	~~System of concepts to support continuity of care~~	To be dropped
7	ISO 13972	Detailed Clinical Models	
8	ISO 20301:2006	Health informatics-Health Cards-General Characteristics	
9	ISO DIS 22857	Health informatics - Guidelines on data protection to facilitate trans- border flows of personal health data	
10	ISO/TS 22220:2008(E)	Health informatics — Identification of subjects of health care	Change in Document Number New Number ISO/TS 22220:2011
11	ISO 13606-1	Health informatics — Electronic health record communication — Part 1:Reference model	
12	ISO DIS 13119	Health informatics — Clinical knowledge resources — Metadata	
13	ISO DIS 22600-1	Health informatics — Privilege management and access control — Part 1: Overview and policy management	
14	ISO DIS 22600-2	Health informatics — Privilege management and access control — Part 2: Formal models	
15	ISO DIS 22600-3	Health informatics — Privilege management and access control — Part 3: Implementations	
16	ISO DTS 14441	Health informatics — Security and privacy requirements of EHR systems for use in conformity assessment	
17	ISO FDIS 17090-1	Health informatics — Public key infrastructure — Part 1: Overview of digital certificate services	

86

S. No.	Doc No	Description	Revisions discussed by IHIN Working Group on EHR
18	ISO FDIS 21549-1	Health informatics — Patient healthcard data — Part 1: General structure	
19	ISO DIS 13940	Health informatics — System of concepts to support continuity of care	
20	ISO 13606-2	Health informatics – Electronic health record communication – Part 2: Archetype interchange specification	To be included
21	ISO 8601	Data elements and interchange formats – Information interchange – Representation of dates and times	To be included

- **Additional ISO Standards**

S. No.	Doc No	Description	Revisions discussed by IHIN Working Group on HER
1	ISO DIS 1828	Health informatics — Categorical structure for classifications and coding systems of surgical procedures	
2	ISO DIS 11616	Health informatics — Identification of medicinal products — Data elements and structures for unique identification and exchange of regulated pharmaceutical product information	
3	ISO DIS 11615	Health informatics — Identification of medicinal products — Data elements and structures for unique identification and exchange of regulated medicinal product information	
4	ISO DIS 11240	Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement	
5	ISO DIS 11238	Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances	
6	ISO FDIS 21090	Health informatics — Harmonized data types for information interchange	
7	ISO DIS 27789.2	Health informatics — Audit trails for	

S. No.	Doc No	Description	Revisions discussed by IHIN Working Group on HER
		electronic health records	
8	ISO 27932: 2009	HL7 Clinical Document Architecture, Release 2	
9	ISO TS 22600: 2006	Privilege management and access control (Parts 1-3)	
10	ISO 27799:2008:	Health informatics -- Information security management in health using ISO/IEC 27002	
11	ISO 17115:2007	Health Informatics-Vocabulary for terminological systems	
~~12~~	~~ISO 17115:2007~~	~~Health Informatics-Vocabulary for terminological systems~~	To be dropped
13	ISO 12052:2006	Health Informatics-Digital Imaging and Communication in medicine (DICOM) including work flow and data management	
14	ISO CD 17583	Health informatics -- Terminology constraints for coded data elements expressed in ISO Harmonized Data Types used in healthcare information interchange	
15	ISO/TS 22220:2008(E)	Health informatics — Identification of subjects of health care	
16	ISO DTS 14441	Health informatics — Security and privacy requirements of EHR systems for use in conformity assessment	

- **Annexure: EHR Minimum Data Set (MDS) ---- the following table shows only those data items where some revision/change has been discussed by the Working Group**

Data Item	Data Type	Data Length	Format/Values	Status	Additional Observations	Revisions discussed by IHIN Working Group on EHR
Patient Name	As specified	As specified	To be split into First Name, Middle Name and Last (Family) Name	Mandatory	MDDS (http://egovstandards.gov.in/standardsandFramework/metadata-and- data-standards/MDDS-Demographic%20Ver%201.1.pdf/at_download/file) may be referred to for patient demographics data; only the person identification part of the meta data and data standards are applicable	MDDS (In PDF format: http://informatics.nic.in/uploads/pdfs/975f38cd_26-27_e-Gov_standards.pdf ; As webpage: https://egovstandards.gov.in/) may be referred to for patient demographics data; only the person identification part of the meta data and data standards are applicable
Patient Occupation	As specified	As specified		Mandatory	It is recommended that MDDS be followed; details are given above	
Patient Address Type	Alphanumeric	9	Current/Permanent /Previous	Mandatory		
Patient Address Line 1	As specified	As specified		Mandatory	It is recommended that MDDS be followed; details are given above	
Patient Address Line 2	As specified	As specified		Optional	It is recommended that MDDS be followed; details are given above	
Patient City/Town/Village/Police Station	As specified	As specified		Mandatory	It is recommended that MDDS be followed; details are given above	

83

Data Item	Data Type	Data Length	Format/Values	Status	Additional Observations	Revisions discussed by IHIN Working Group on EHR
Clinical Exam Observation	Alphanumeric	4096		Mandatory	It is recommended that SNOMED-CT be used for all clinical terms/observations	All clinical terms to be SNOMED CT compliant; while all clinical data must be stored as conceptID or descriptionID of SNOMED CT, these should be displayed using the description
Clinical Summary	Alphanumeric	4096		Mandatory	It is recommended that SNOMED-CT be used for all clinical terms/observations	All clinical terms to be SNOMED CT compliant; while all clinical data must be stored as conceptID or descriptionID of SNOMED CT, these should be displayed using the description
Diagnosis Type	Alphanumeric	11	Provisional/Final/Admission/Interim/ Working/Discharge	Mandatory		It is recommended that LOINC be used for all laboratory observations
Diagnosis Code Name	As specified	As specified	ICD/SNOMED CT/Free	Mandatory	This denotes the name of the diagnosis coding system – SNOMED-CT/ICD, etc. It is recommended that SNOMED-CT be used. Till such time SNOMED-CT license is procured, it is recommended that ICD be used	This denotes name of the diagnosis coding system – SNOMED-CT and/or ICD. The vendors are free to choose either system for diagnosis as per their system and/or client requirement
Diagnosis Code	As specified	As specified	Coding system dependent	Mandatory	Diagnosis Code should allow multiple entries per encounter record	Diagnosis Code should allow multiple entries per encounter record
Diagnosis (Description)	Alphanumeric	4096		Mandatory		The corresponding description as per the code – SNOMED-CT or ICD – used

82

Data Item	Data Type	Data Length	Format/Values	Status	Additional Observations	Revisions discussed by IHIN Working Group on EHR
Treatment Plan Investigations	Alphanumeric	4096		Mandatory in Inpatients settings, Optional in others	The user may or may not enter any value	Where used, all investigation names terms to be LOINC compliant; Vendors may choose to use SNOMED-CT instead, in which case, LOINC-SNOMED CT mapping capabilities will need to be built-in to permit interoperability
Treatment Plan Medication	Alphanumeric	4096		Mandatory	It is preferable that the details are captured in as granular a manner as is practical; for the allopathic system of medicine, it is suggested that something similar to the contents of the table below be followed - this requirement is not mandatory	It is preferable that the details are captured in as granular a manner as is practical; for the allopathic system of medicine, it is suggested that something similar to the contents of the table below be followed - this requirement is not mandatory. Where used, all clinical terms to be SNOMED CT compliant for all allopathic treatment
Treatment Plan Procedure	Alphanumeric	4096		Mandatory in Inpatients settings, Optional in others	Should be “None” if no procedure is advised/dispensed	Should be “None” if no procedure is advised/dispensed. Where used, all clinical terms to be SNOMED CT compliant for all allopathic treatment
Treatment Plan Referral	Alphanumeric	4096		Optional	For use in referral cases only	For use in referral cases only
Other Treatment Plan Type	Alphanumeric	10	Diet/Life-style/ Others	Optional		Where used, all clinical terms to be SNOMED CT compliant for all
Other Treatment Plan Details	Alphanumeric	4096		Mandatory if Other Treatment Type is		Where used, all clinical terms to be SNOMED CT compliant

Data Item	Data Type	Data Length	Format/Values	Status	Additional Observations	Revisions discussed by IHIN Working Group on EHR
Current Clinical Status / Oulook	Alphanumeric	255	The appropriate prognosis/outlook finding to be used	Mandatory	Captures the current clinical status; synonymous with clinical outcome or condition at discharge; it is preferable that terms such as “Fair”, “Relieved”, “Better”, “Same”, “Worse”, “Fatal”, etc. be used instead of long narratives	Captures the current clinical outlook or prognosis. Only SNOMED CT to be used
Care Provider Digital Signature	As appropriate	As appropriate	As appropriate	Mandatory only for records related to MLC; optional	Please refer to the Digital Signatures section in Chapter 7 – Data Ownership	Please refer to the Digital Signatures section in Chapter 4 – Data Ownership

- **Medication Details**

Data Item	**Data Type**	**Data Length**	**Format/Values**	**Status**	**Additional Observations**	**Revisions discussed by IHIN Working Group on EHR**
Medication Name	As specified	As specified	As per the drug database	Optional; if entered, then some fields are	Should preferably be generic	Should be as per SNOMED CT
Drug Code	As specified	As specified	As per the drug database	Mandatory, if entered	Auto populated by the system	Should be as per SNOMED CT
Drug Identifier	As specified	As specified		Optional	GS1 bar/QR code	As per the GS1 specified d data structure
Strength	As specified	As specified	As per the drug database	Mandatory, if entered	Should be presented as a LOV	Should be as per SNOMED CT
Dose	As specified	As specified		Mandatory, if entered	To be entered by the care provider	
Route	As specified	As specified		Mandatory, if entered	To be entered by the care provider	Should be as per SNOMED CT
Frequency	As specified	As specified		Mandatory, if entered	To be entered by the care provider	Should be as per SNOMED CT
Duration	As specified	As specified		Mandatory, if entered	To be entered by the care provider; this represents the length of time the	Should be as per SNOMED CT

79

Q-11011/3/2015-eGov
Government of India
Department of Health and Family Welfare
e-Governance Division
*****

Nirman Bhawan, New Delhi
Dated: 24th August, 2015

Meeting Notice

Subject: Meeting of EHR Review Committee on 26th August, 2015 at 04.00 PM in Nirman Bhawan, New Delhi.

Ministry of Health and Family Welfare notified Electronic Health Record (EHR) Standards in September 2013 to encourage standardization, integration and electronic information exchange amongst the various healthcare providers.

2. EHR Review Committee has been constituted vide order even number dated 05.08.2015 (Copy enclosed) with the approval of Secretary (HFW) to review the aforementioned standards. The first meeting of the EHR Review Committee under the Chairmanship of Shri N B Dhal, JS (eGov) has been scheduled at 04.00 PM on 26th August, 2015 in Room No 406-A wing, Nirman Bhawan, New Delhi.

3. You're requested to kindly take part in the meeting as a 'special invitee' as per the above schedule.

(Jitendra Arora)
Director (eGov)
Tel No.23062317

To:

1. Mr Sanjiv Mital, CEO, NISG
2. Ms Shobha Mishra Ghosh, Senior Director, FICCI
3. Dr Rajesh Narwal, Technical Director, Health System Regulations, WHO
4. Mr Amit Mishra, Senior Consultant, NHSRC

Copy to,

1. PPS to AS (KBA), MoHFW
2. PPS to JS (eGov), MoHFW

78

Gmail by Google

Nikunja Dhal <jsnbdhal@gmail.com>

EHR standards and eHealth initiatives

1 message

NARWAL, Rajesh <narwalr@who.int> Thu, Aug 6, 2015 at 5:21 PM
To: "nbdhal@gmail.com" <nbdhal@gmail.com>, "jsnbdhal@gmail.com" <jsnbdhal@gmail.com>

Dear Mr Dhall,

Greetings from WHO country office for India!

At the outset, I would like to congratulate you on establishing the India Health Information Network (IHIN) which is critical for taking the eHealth related initiatives forward- including the NeHA and release of EHR standards. WHO is represented on three out of 4 working groups under IHIN and continues to contribute.

As you know, WHO HQ (Dr Najeeb-Al-Shorbaji) and India also provided technical inputs remotely and in the meetings while the SNOMED-CT standards for EHR were procured. However as also highlighted in the IHIN Working group meetings, the EHR standards prepared in 2013 are bit dated, since SNOMED-CT was procured later on only. I have been discussing it with other domain experts in WHO and outside, and there is a general consensus that the EHR standards in India need to be updated and released at the earliest. This is aligned to the New National Health Policy and EHRs are also a prerequisite under the Government of India's Clinical Establishment Act (CEA) -2010. WHO, MoHFW and NIHFW are conducting a study on CEA, which identifies lack of EHR standards as one of the contentious aspects and a major reason behind sub-optimal adoption and implementation of CEA in states.

Electronically capturing each health transaction between patient and provider is not only necessary for effective health service delivery and continuum of care but also for improving transparency and accountability, besides strengthening the availability of health Information in India. It would be good to expedite the finalization and release of the draft EHR standards, before healthcare providers/hospitals progress on using their own/standalone EHR systems which may be difficult to revert and could hamper interoperability of legacy data.

With these views, may I please seek your convenience for a brief meeting to discuss potential ways in which MoHFW and WHO could coordinate efforts for taking these initiatives forward.

pl. speak

Dir(egov)

Thank you

US(eGov)-OL

With kind regards

Rajesh

AD(e-Gov) 13/8/15

Dr Rajesh Narwal, MD, MPH

Technical Officer- Health Systems Stewardship and Regulations

72

World Health
Organization

Cou[illegible]ry Office- India

Phone: +91 11 66564800, GPN: 23232

Fax: +91 11 26162996

Mob (off.): +91 9871968672

Web: http://www.searo.who.int/india/en/

स्पीड पोस्ट द्वारा
BY SPEED POST

18 AUG 2015
ISSUED

O/c

76

Q-11011/3/2015-eGov
Government of India
Department of Health and Family Welfare
e-Governance Division
*****

Nirman Bhawan, New Delhi
Dated: 18th August, 2015

Meeting Notice

Subject: **Meeting of EHR Review Committee on 26th August, 2015 at 04.00 PM in Nirman Bhawan, New Delhi.**

Ministry of Health and Family Welfare notified Electronic Health Record (EHR) Standards in September 2013 to encourage standardization, integration and electronic information exchange amongst the various healthcare providers.

2. EHR Review Committee has been constituted vide order even number dated 05.08.2015 (Copy enclosed) with the approval of Secretary (HFW) to review the aforementioned standards. The first meeting of the EHR Review Committee under the Chairmanship of Shri N B Dhal, JS (eGov) has been scheduled at 04.00 PM on 26th August, 2015 in Room No 406-A wing, Nirman Bhawan, New Delhi.

3. All the addressees are requested to kindly make it convenient to attend the meeting as per the above schedule.

18|8|15
(Amit Kumar)
AD (eGov)
Tel No.23062263

To:

1. Dr Supten Sarbadhikari, Project Director (NHP), NIHFW
2. Dr. S B Bhattacharya, Head Health Informatics, TCS
3. Dr B.S. Bedi, Advisor, CDAC, Delhi
4. Shri. Gaur Sunder, CDAC, Pune
5. Shri. Sunil Kumar Bhushan, NIC, Health
6. Dr. Karanvir Singh, CIO, Apollo Hospitals
7. Shri Jitendra Arora, Director (eGov), MoHFW 18/8/15
8. PL (ePMU team), MoHFW

Copy to:

1. Secretary (DeitY) - with a request that an officer of Director level may kindly be nominated for EHR review committee as requested earlier vide order even number dated 05.08.2015.
2. PPS to JS (eGov), MoHFW

FTS : 66790

Pls Issue e&I
By Speed post
18-8-15

Copy for Kind Information:

1. PPS to Secretary (HFW), MoHFW 18/8
2. PPS to AS (KBA), MoHFW 18/8/15

75

Subject: **Meeting of EHR Review Committee on 26th August, 2015 at 04.00 PM in Nirman Bhawan, New Delhi.**

Date: 08/18/15 12:29 PM
From: Amit Kumar <amit.k89@gov.in>

To: supten@nihfw.org, supten@gmail.com,
ankit_tripathi11@hotmail.com, sbbhattacharyya@gmail.com,
gaurs@cdac.in, bedi11@yahoo.com,
Sunil Kumar <sunil.bhushan@gov.in>,
drkaranvir_s@apollohospitals.com,
Jitendra Arora <dir.ehealth@gmail.com>,
chandrasens@deloitte.com, nimalhotra@deloitte.com,
bhanuprakash@deloitte.com
Cc: "DIT, Secretary DIT" <secretary@deity.gov.in>,
secretary@mit.gov.in, secyhfw@gmail.com,
NB Dhal <nbdhal@gmail.com>

EHR meeting notice 26.08.15.pdf (295kB) EHR Review Committee.pdf (569kB)

Q-11011/3/2015-eGov

Government of India

Department of Health and Family Welfare

e-Governance Division

*****

Nirman Bhawan, New Delhi

Dated: 18th August, 2015

Meeting Notice

Subject: Meeting of EHR Review Committee on 26th August, 2015 at 04.00 PM in Nirman Bhawan, New Delhi.

Ministry of Health and Family Welfare notified Electronic Health Record (EHR) Standards in September 2013 to encourage standardization, integration and electronic information exchange amongst the various healthcare providers.

2. EHR Review Committee has been constituted vide order even number dated 05.08.2015 (Copy enclosed) with the approval of Secretary (HFW) to review the aforementioned standards. The first meeting of the EHR Review Committee under the Chairmanship of Shri N B Dhal, JS (eGov) has been scheduled at 04.00 PM on 26th August, 2015 in Room No 406-A wing, Nirman Bhawan, New Delhi.

3. All the addressees are requested to kindly make it convenient to attend the meeting as per the above schedule.

To:

1. Dr Supten Sarbadhikari, Project Director (NHP), NIHFW
2. Dr. S B Bhattacharya, Head Health Informatics, TCS
3. Dr B.S. Bedi, Advisor, CDAC, Delhi
4. Shri. Gaur Sunder, CDAC, Pune
5. Shri. Sunil Kumar Bhushan, NIC, Health
6. Dr. Karanvir Singh, CIO, Apollo Hospitals
7. Shri Jitendra Arora, Director (eGov), MoHFW
8. PL (ePMU team), MoHFW

Copy to:

1. Secretary (DeitY) - with a request that an officer of Director level may kindly be nominated for EHR review committee as requested earlier vide order even number dated 05.08.2015.
2. PPS to JS (eGov), MoHFW

Copy for Kind Information:

1. PPS to Secretary (HFW), MoHFW
2. PPS to AS (KBA), MoHFW

Regards

Amit Kumar

Assistant Director (eGovernance)

Ministry of Health & Family Welfare

Room No. 425C

Nirman Bhawan

New Delhi – 110 011

Tel: 011 – 2306 2263

Mobile: 9582861973

Office Copy

Subject: Constitution of EHR Committee.

S.No	Name	Designation	Room No	FTS	Sign
1. ✓	Shri Navreet Singh Kang	AS&DG	257-A	192032(3)	
2. ✓	Shri N B Dhal	JS	103-D	192032	NB
3. ✓	Shri Jitendra Arora	Director	307-D	192032(1)	
4.	Shri Supten Sarbadhikari	PD (CHI)	Baba Ganganath Marg, Near DDA Flats, Munirka, New Delhi, Delhi 110067	64165	
5.	Dr. S. B. Bhattacharya	Head, HI, TCS	Tata Consultancy Services,4th & 5th Floor, PTI Building,4 Parliament Street,New Delhi 110 001	64166	
6.	Mr. B.S. Bedi	Advisor, (CDAC)	C-48 Tarang Aptt. 19 IP Ext Patparganj, Delhi 110092	64167	
7.	Mr Gaur Sunder	Principal Technical officer	VC & BA group C-DAC Westend Center 3 nagaras road aundh Pune 411007	64168	
8.	Dr. Karanvir Singh	CMIO Apollo Hospitals	Mathura Road, Sarita Vihar New Delhi 110076	64169	
9.	Shri R S Sharma	Secretary, DeitY	Ministry of Communications & Information Technology ,Electronics Niketan, 6, CGO Complex, Lodhi Road, New Delhi: 110003	64172	
10. ✓	Shri Sunil Bhusan	STD(NIC)	146-A	192032(2)	10/08/15

Please Issue R&I
By speed post

10-8-15

11/08/15

स्पीड पोस्ट द्वारा
BY SPEED POST

स्वास्थ्य एवं परिवार कल्याण मंत्रालय
जारी किया
10 AUG 2015
ISSUED
MINISTRY OF HEALTH & F.W.

No.Q-11011/3/2015-eGov
Department of Health and Family Welfare
e-Governance Section
****

Nirman Bhawan, New Delhi
Date: 05 .8.2015

ORDER

Ministry of Health and Family Welfare notified the Electronic Health Records (EHR) Standards in September, 2013 to encourage standardisation, integration and electronic information exchange amongst the various healthcare providers.

2. Subsequently, India became a member of International Health Terminology Standards Development Organisation (IHTSDO), Denmark with effective from 01.04.2014 which owns and administers the rights to SNOMED CT. All the vendors and Healthcare professionals of India can use SNOMED CT for Health IT applications to be used in India without paying any licence fee.

3. Since EHR is a living document and should be reviewed/updated periodically for ensuring compliance with prevailing global standards, devices and equipments, it has been decided with the approval of the competent authority to constitute a Committee to review the EHR Standards notified by this Ministry in 2013. The composition of the EHR Committee is as under:

(i)	Shri N.B. Dhal, JS(eGov), DoHFW	Chairman
(ii)	Dr. Supten Sarbadhikari, Project Director (NHP), NIHFW	Member
(iii)	Dr. S.B. Bhattacharya, Head, Health Informatics, TCS	Member
(iv)	Dr. B.S. Bedi, Advisor, C-DAC, Pune	Member
(v)	Shri Gaur Sunder, C-DAC, Pune	Member
(vi)	Shri Sunil Kumar Bhushan, NIC, D/o HFW	Member
(vii)	Dr. Karanvir Singh, CIO, Apollo Hospitals	Member
(viii)	Representative of DeitY	Member
(ix)	Shri Jitendra Arora, Director, D/o HFW	Convener

(41)

4. **Payment:** All non-official members of the Sub Groups, who are outstation will be eligible for reimbursement of air travel by the economy class/shortest direct route. All non-official members will be eligible for reimbursement @Rs.1500/- per diem as sitting fee for attending the Committee meetings. Outstation non-official members will also be entitled for reimbursement of hotel accommodation expenses as per actual subject to a ceiling of Rs.6500/-. TA/DA of official members of the Sub-Groups for attending the meetings shall be met from the same source from which their salary is drawn.

(Jitendra Arora)
Director
Tel.No.23062317

To:

The Chairman and all the Members of the EHR Review Committee

Copy to:

Secretary, Department of Electronics and Information Technology(DeitY), Electronics NIketan, 6 CGO Complex, Lodhi Road, New Delhi-03. It is requested that an officer of Director level may kindly be nominated for the EHR Review Committee.

Copy for kind information to: PPS to AS&DG/PPS to JS(eGov)

70

Subject: **Constitution of EHR Review Committee in the Department of Health and Family Welfare**
Date: 06/08/15 04:31 PM
From: Sunita Dhaundiyal <sunita.dhaundiyal@nic.in>
To: secretary@deity.gov.in
Cc: JITENDRA ARORA DIRECTOR <jitendra.arora@gov.in>, amit.k89@gov.in <amit.k89@gov.in>

EHR Review Committee.pdf (569kB)

Sir,

I am directed to attach Ministry of Health and Family Welfare's Order No.Q-11011/3/2015-eGov dated 5.8.2015 constituting EHR Review Committee in this Department with the request that a Director level Officer of the Department of Electronics and Telecommunications may kindly be nominated for the Committee.

Regards,

Sunita Dhaundiyal
US(eGov)
Department of Health and Family Welfare
Tel No.23062317

Subject: **Constitution of EHR Review Committee in the Ministry of Health and Family Welfare regarding**

Date: 06/08/15 04:21 PM

From: Sunita Dhaundiyal <sunita.dhaundiyal@nic.in>

To: jsnbdhal@gmail.com, supten@gmail.com, sbbhattacharyya@gmail.com, Bedi11@yahoo.com, gaurs@cdac.in, sunil.bhushan@nic.in, karanvir.singh@gmail.com, dir.ehealth@gmail.com

Cc: amit.k89@gov.in <amit.k89@gov.in>, Chandrasen (IN - Delhi) Shrivastava <chandrasens@DELOITTE.c

EHR Review Committee.pdf (569kB)

Sir

Please find attached Ministry of Health and Family Welfare's Order No.Q-11011/3/2015-eGov dated 5.8.2015 on the subject mentioned above for information.

Regards,

Sunita Dhaundiyal
Under Secretary (eGov)
D/o Health and Family Welfare
Tel. No.23061843

68

Z.28011/5/2010-CBHI (Pt.-2)

Reference IFD's remark at pre-page:

Page-7/Note ante

The proposal is regarding enhancement of allowance to the members of the Fourth Sub Group i.e. Legal Sub Group for Electronic Health Record (EHR) standards. This Sub-Group has been formed with the approval of Secretary (HFW).

Flag 'X'

2. Earlier MoHFW constituted a committee of experts for developing EHR standards. The committee in turn formed three (3) sub groups in 2010 to look into the three aspects viz. standards, data connectivity and data ownership. The committee submitted its recommendations to MoHFW based on which EHR standards for India were notified in August 2013. On completion of the said task these sub groups were dissolved.

3. As the MoHFW is now in the implementation phase of EHR standards of India, there is a need for constitution of Fourth Sub Group i.e. Legal Sub Group which will look into the accessibility, privacy and confidentiality of the patient health records (PHR). A brief on EHR and its current status note is placed at 'F/A' for perusal.

Flag 'Y'

4. In terms of financial aspect the three sub groups were constituted in 2010 with the facility for reimbursement of air travel for the non-official outstation members by economy class/shortest direct route and per diem @ Rs 1000/- as sitting fee and for hotel accommodation expenses as per actual subject to ceiling of Rs 5000/-.

5. It is now recommended that the same be revised for the fourth sub group that has recently been constituted, with reimbursement of air travel for the non-official outstation members by economy class/shortest direct route and per diem @ Rs 1500/- as sitting fee and for hotel accommodation expenses as per actual subject to ceiling of Rs.7500/- in view of general increase in prices and inflation from the year 2010 to current year 2014. TA/DA for the official members of the sub group for attending the meeting shall be met from the same source from which their salary is drawn.

Flag 'Z' & 'B'

6. As per GOI's Order, the rate of Daily allowance (DA) (SR51) for Officers drawing grade pay of Rs.10,000 and above and those in pay scales of HAG+ and above is as follows:

> *"Reimbursement for Hotel accommodation/guest house of upto Rs.5,000/- per day"; reimbursement of AC taxi charges of up to 50 kms. for travel within the city and reimbursement of food bills not exceeding Rs.500/- per day.*
>
> Further, *"These rates shall automatically increase by 25% whenever the Dearness Allowance payable on the revised pay structure goes up by 50%."*

Following this norm, the reimbursement of Hotel accommodation/guest house calculates upto Rs.7,500/- per day in accordance with present DA structure.

P.T.O

7. It is seen from the composition of the 4th Sub-Group (Legal) that the non-official members of the Steering Committee are of very senior rank, so the DA to them may be reimbursed for attending the meetings of the Sub-Group as per the norms as stated in para-6 above.

8. In view of para.6 & 7 above, the proposal is for consideration and concurrence of IFD as it involves financial enhancement:

S.No.	Item	Existing Rate	Proposed Rate	Reason
1.	Sitting fee to non-official members for attending the meeting	Rs.1000/- per diem	Rs.1500 per diem	General increase in prices and inflation from the year 2010.
2.	Hotel accommodation guest house expenses	As per actual subject to a ceiling of Rs.5000/-	As per actual subject to a ceiling of Rs.6500/-	As per GOI instructions on Daily Allowance rate.

1x

Before the file is sent to IFD, kind approval of JS(e gov) may be solicited.

(Soma Sanyal)
US(e/Gov./TM)
14.08.14

Dir(eGov.)

14/8/14

JS(eGov)

14/8

IFD

(I.F.D.)
Dy/FTS No. 8187/IFD
Date 19/8/14

-11-

66

INTEGRATED FINANCE DIVISION

Reference note at 9-10 /N ante.

The proposal in file relates to enhancement of allowance to the members of the Fourth Sub Group i.e. Legal Sub Group for Electronic Health Record (EHR) standards. This Sub Group has been formed with the approval of Secretary(H).

In terms of financial aspect the three sub groups were constituted in 2010 with the facility for reimbursement of air travel for the non-official outstation members by economy class/shortest direct route and per diem @ Rs.1000/- as sitting fee and for hotel accommodation expenses as per actual subject to ceiling of Rs.5000/-.

It is now proposed that the same be revised for the fourth sub group that has recently been constituted, with reimbursement of air travel for the non official outstation members by economy class/shortest direct route and per diem @ Rs.1500/- as sitting fee and for hotel accommodation expenses as per actual subject to ceiling of Rs.6500/- in view of general increase in prices and inflation from the year 2010 to current year 2014. TA/DA for the official members of the sub group for attending the meeting shall be met from the same source from which their salary is drawn.

As per GoI's Order, the rate of Daily Allowance (DA) (SR51) fro Officers drawing grade pay of Rs.10,000/- and above and those in pay scales of HAG+ and above is as follows:-

"Reimbrusement for hotel accommodation/guest house of upto Rs.5000/- per day" reimbursement of AC taxi charges of up to 50 kms. for travel within the city and reimbursement of food bills not exceeding Rs.500/- per day.

Further, "These rates shall automatically increase by 25% whenever the Dearness Allowance payable on the revised pay structure goes up by 50%."

In view of above IFD may agree to the proposal made at 'X' on 10/N ante.

Submitted for consideration and approval please.

Min. of Health & F.W.
A.S. & FA's Office
FTS No. 5976
Date 20/8/14

(M. S.Shamsi)
US (F-III)/19.8.2014

C-992
21/8/14

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Z.28011/5/2010-CBHI Part-2
Government of India
Department of Health and Family Welfare
*****

Nirman Bhawan, New Delhi
Dated: 01st September, 2014

Office Memorandum

Subject: Constitution of Fourth Sub Group under EHR/EMR Standards Committee

The "Electronic Health Record (EHR) Standards for India" were notified by Ministry of Health & Family Welfare, Government of India in August 2013. It is recognized that issues relating to security and confidentiality of the electronic health records are extremely relevant for implementation of the standards.

2. In this regard, three sub groups have already been formed for EHR standards vide OM No. Z.28015/79/2010-Hosp. dated 19/10/2010.

3. It is now decided to constitute the Fourth sub-group, i.e "Legal sub-group" which will look into accessibility, privacy and confidentiality of the patient data. The composition of the Fourth sub-group proposed to carry out the said activity is as follows:

1	Shri R.K. Jain, AS&DG(CGHS), Ministry of Health & Family Welfare, New Delhi	Chairman
2.	Shri K.L. Sharma, Joint Secretary (Regulation), Ministry of Health & Family Welfare, New Delhi	Member
3.	Mr. B.S. Bedi, Advisor, Centre for Development of Advanced Computing	Member
4.	Mr. V P Singh, Assoc. Professor, Dept. of Forensic Medicine, Dayanand Medical College & Hospital , Ludhiana	Member
5.	Mr. Arvind Sivaramakrishnan, Chief Information Officer, Apollo Hospitals Enterprise Ltd, Chennai	Member
6.	Prof. Naresh Gupta, Director – Professor, Maulana Azad Medical College and Associated Hospital, New Delhi	Member
7.	Representative, UIDAI, New Delhi	Member
8.	Representative, DeitY, New Delhi	Member

4. Terms of reference of the Legal Sub-Group are as follows:

- Review of the relevant legal provisions
- Other issues relating to confidentiality, security of patient health records and access thereto.

64

Payment: All non-official members of the Sub-Groups, who are outstation, will be eligible for reimbursement of air travel by the economy class / shortest direct route. All non-official members will be eligible for reimbursement @ Rs. 1500/- per diem as sitting fee for attending the Sub-Group's meetings. Out station non-official members will also be entitled for reimbursement of hotel accommodation expenses as per actual subject to a ceiling of Rs. 6500/-. TA/DA of official members of the Sub-Groups for attending the meetings shall be met from the same source from which their salary is drawn.

This issues with the approval of Secretary (HFW).

(Jitendra Arora)
Director (eGov)

To:

1) All Members of Legal Sub Group (as per list attached)
2) All Members of EHR Standards Committee (as per list attached)

Copy to:

1) Secretary, Department of Electronics and Information Technology, Electronics Niketan, 6 CGO Complex, Lodi Road, New Delhi – 110003. **It is requested that an officer of Director Level and above may kindly be nominated for Legal Sub Group.**

2) Director General, Unique Identification Authority of India, Planning Commission, Government of India,3rd Floor, Tower II, Jeevan Bharati Building, Connaught Circus, New Delhi – 110001. **It is requested that an officer of Director Level and above may kindly be nominated for Legal Sub Group.**

3) Shobha Mishra Ghosh, Senior Director, FICCI, New Delhi.

Copy for kind information to:

1) PPS to AS&DG(CGHS)
2) PPS to JS(NBD)

GO related to Sub-Groups Formation

Government of India
Ministry of Health and Family Welfare
Department of Health and Family Welfare
Nirman Bhawan, New Delhi-110108

No. Z.28015/79/2010-Hosp. ***Dated:*** 19 /10/2010

OFFICE MEMORANDUM

Subject: - Standardization of Electronic Medical Records.

The undersigned is directed to refer to the decisions taken in the 1st meeting of EMR Standards Committee dated 30th Sept., 2010 regarding constitution of Sub-Groups for taking up various tasks for development of EMR standards. It has been decided to constitute the following Sub-Groups with the composition given herein as under:

Sub-Groups for Development of EMR Standards

Tasks	Members of Sub Group	Group Head
Task 1: Standards Terminology, Coding standards et al.	1. Prof. Dr. S.V. Mani 2. Dr. R.R. Sudhir 3. Ms. Kala Rao 4. Dr. Ashok Kumar 5. Ms. Shobha Mishra Ghosh, FICCI 6. Dr. Sameer A. Khan	Prof. Dr. S.V. Mani, TCS
Task 2 : Data connectivity Including hardware, software and interoperability.	1) Dr. B.S. Bedi 2) Dr.Supten Sarbadhikari 3) Dr. S.B. Bhattacharya 4) Dr. Thanga Prabhu 5) Mr. Sunder Gaur 6) Mr. S.K.Dhar, NIC	Dr. B.S. Bedi, CDAC
Task 3: Data ownership Data protection and security including legal aspects/complaints, guidelines and reports already available.	1. Prof. Saroj K. Mishra 2. Prof. Indrajit Bhattacharya 3. Prof. Sita Naik, MCI 4. Dr. Karanveer Singh 5. Dr. Naveen Jain, CDAC 6. Dr. Arun Bal 7. Mr. Madhu Aravind	Prof. S.K. Mishra, SGPGI

Contd...2/-

The Group Heads and the members of the sub groups are requested to complete the tasks assigned to them within the stipulated time frame as per the TOR.

Payment : All non-official members of the Sub-Groups, who are outstation, will be eligible for reimbursement of air travel by the economy class / shortest direct route and per diem @ Rs. 1000/- and other non-official members per diem @ Rs. 1000/- for the Sub-Group's meetings. Out station non-official members will also be entitled for reimbursement of hotel accommodation expenses as per actual subject to a ceiling of Rs. 5000/-. TA /DA of official members of the Sub-Groups for attending the meetings shall be met from the same source from which their salary is drawn.

This issues with the approval of Secretary (Health & Family Welfare).

(V. P. Singh)
Deputy Secretary to the Govt. of India
Ph. No.2306 2791

To

All the members of the EMR Standard Committee / Sub-Groups (As per list)

Copy to: -

PPS to HFM/ PPS to MOS(DT)/ PPS to Secretary (H&FW)/
PPS to DGHS/ PPS to AS & DG, CGHS /PS to JS (H)

14. Annexures

Government of India
Ministry of Health and Family Welfare
Department of Health and Family Welfare
Nirman Bhawan, New Delhi-110108

No. Z.28015/79/2010-Hosp. ***Dated:*** 13 /09/2010

OFFICE MEMORANDUM

Subject: - Standardization of Electronic Medical Records.

The undersigned is directed to refer to the meeting of Experts held on 10th August, 2010 under the chairpersonship of Secretary (Health & Family Welfare) wherein it has been decided to constitute a Committee of Experts for development of an Information Technology (IT) based electronic medical records maintenance system for hospitals.

There is a need to initiate a project for developing an IT enabled uniform system of electronic medical records maintenance for hospitals that will maintain the records of treatment, identification, healthcare providers, cost of treatment, standard of healthcare availability and quality of treatment etc. Availability of electronic medical records will help data monitoring of available information to enforce the Standard Treatment Protocols which are separately being developed under the guidance of a Core Committee of Experts constituted under the chairpersonship of Secretary (Health & Family Welfare).

Accordingly, the Govt. have decided to constitute a Committee of Experts for development of standards on electronic medical records (EMR) maintenance system for hospitals. The composition of the Committee and its Terms of Reference are as under:

Sl. No.	Name	
1.	Mr. L.C. Goyal,	Chairman

	Additional secretary & DG, CGHS Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi.	
2.	Dr. D.C. Jain, Spl. DG Directorate General of Health Services, Nirman Bhawan, New Delhi	Co-Chairman
3.	Dr. B. S. Bedi, Vice President, Telemedicine Society of India and Advisor- Health Informatics CDAC, Govt. of India. bedi11@yahoo.com	Member
4.	Dr. R. R. Sudhir, Sr. Consultant-Cornea Deptt. Sankara Nethralaya drrrs@snmail.org	Member
5.	Dr. S.B. Bhattacharya, President, Indian Association of Medical Health	Member
6.	Ms. Sangeeta Reddy, Executive Director,Apollo Hospitals sangita_reddy@apollohealthstreet.com	Member
7.	Dr. Supten Sarbadhikari Director,CAL2CAL Group supten@cal2cal.com	Member
8.	Dr. Thanga Prabhu Clinical Director - Healthcare IT GE Healthcare arokiaswamy.thangaprabhu@ge.com	Member
9.	Prof. Saroj K. Mishra Head, School of Telemedicine and Biomedical Informatics, Sanjay Gandhi PG Inst. of Medical Sciences skmishra@sgpgi.ac.in	Member
10.	Prof. Indrajit Bhattacharya Professor, IIHMR indrajit@iihmr.org	Member
11.	Dr. Sameer A. Khan, Director Medical Technology & Planning Fortis Healthcare Limited sameer.khan@fortishealthcare.com	Member
12.	Mr. Madhu Aravind, CEO HealthHiway madhu@healthhiway.com	Member
13.	Ms Kala Rao, Sr Consultant, TCS sumanth.raman@tcs.com	Member
14.	Mr. Jay Kumar	Member

59

	Dy. Director, Insurance Information Bureau, IRDA, Hyderabad	
15.	Ms. Jyoti Vij, Asst Secretary General, FICCI, New Delhi jyoti@ficci.com	Member
16.	Mr. Y.K. Sharma, DDG, NIC, New Delhi	Member
17.	Mr. Sunder Gaur, Head, Medical Informatics, CDAC, Pune	Member
18.	Dr. Ashok Kumar Director, CBHI, New Delhi	**Convenor**

58

Government of India
Ministry of Health and Family Welfare
Department of Health and Family Welfare
Nirman Bhawan, New Delhi-110108

CIRCULAR

Government of India intends to introduce a uniform system for maintenance of Electronic Medical Records / Electronic Health Records (EMR / EHR) by the Hospitals and healthcare providers in the country. An Expert Committee was set up to develop EMR / EHR Standards for adoption /implementation in the country. Draft EMR/EHR Standards were hosted on the website of the Ministry soliciting comments from the stakeholders and general public. After due consideration of the recommendations of the Committee and the comments received thereon, the '**Electronic Health Record Standards for India**' have been finalised and approved by the Ministry of Health and Family Welfare, Government of India.

A copy of the above document is placed herewith for information of all healthcare providers, medical professionals and other stakeholders for adoption and implementation in the healthcare institutions across the country in public interest.

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(57)

Electronic Health Record Standards For India

August 2013

Approved by Ministry of Health & Family Welfare,
Government of India

TABLE OF CONTENTS

1. EXECUTIVE SUMMARY 3
2. INTEROPERABILITY AND STANDARDS 4
Goals 4
Categories for adoption of standards 5
3. GUIDELINES 13
Hardware 13
Networking and Connectivity 13
Software Standards 13
Proposed Mobile Health Record 14
4. DATA OWNERSHIP OF EHR 15
5. DATA PRIVACY & SECURITY 20
6. REFERENCES 23
7. ANNEXURE: EHR MINIMUM DATA SET (MDS) 24
10. ACRONYMS, DEFINITIONS & GLOSSARY 39
11. FORMAT FOR MEDICAL RECORDS 54

LIST OF TABLES

Table 1: HCIT Standards (applicable in India) 8
Table 2: Additional ISO Standards 9
Table 3: ISO Standards Already Considered 10
Table 4: Organisations and their recommended Health Informatics Standards 12
Table 5: Patient Identifying Information 19
Table 6: EHR MDS 37

55

1. EXECUTIVE SUMMARY

Healthcare systems are highly complex, fragmented and use multiple information technology systems. With vendors incorporating different standards for similar or same systems, it is little wonder that all-round inefficiency, waste and errors in healthcare information and delivery management are all too commonplace an occurrence. Consequently, a patient's health information often gets trapped in silos of legacy systems, unable to be shared with members of the healthcare community. These are some of the several motivations driving an effort to encourage standardization; integration and electronic information exchange amongst the various healthcare providers.

The study termed as Developmental Origins of Health and Diseases or DOHAD has successfully proven the importance of developmental records of individuals in predicting and/or explaining the diseases that a person is suffering from. In the current largely paper-based health records world, invaluable data is more often than not unavailable at the right time in the hands of the clinical care providers to permit better care. This is largely due to the inefficiencies inherent in the paper-based system. In an electronic world, it is very much possible, provided certain important steps are taken beforehand, to ensure the availability of the right information at the right time.

In order to be meaningful, the health record of an individual needs to be from conception (better) or birth (at the very least). As one progresses through one's life, every record of every clinical encounter represents an event in one's life. Each of these records may be insignificant or significant depending on the current problems that the person suffers from. Thus, it becomes imperative that these records be arranged chronologically to provide a summary of the various clinical events in the lifetime of a person.

Electronic health records are a summary of the various electronic medical records that get generated during any clinical encounter. Without standards, a lifelong summary is not possible as different records from different sources spread across ~80+ years will potentially need to be brought into one summary. To achieve this, a set of pre-defined standards for information exchange that includes images, clinical codes and a minimum data set is imperative.

The health data is owned by the patient while the actual records are owned by the care providers who act as the custodians of the data. For creation of a true electronic health record of an individual it is imperative that all clinical records created by the various care providers that a person visits during his/her lifetime be stored in a central clinical data repository or at least be shareable through the use of interoperable standards. Adequate safeguards to ensure data privacy and security must strictly be adhered to at all times. Patients must have the privilege to verify the accuracy of their health data and gain access whenever they wish to do so.

While any vendor may choose to have any additionally relevant information captured and presented, all must conform to the MDS. A short reference section and a detailed section of acronyms, definitions and glossary are added for everyone's benefit.

It must be noted that these standards must not be considered either in isolation or being *"etched in stone for all eternity"*. These will undergo periodic (at a maximum of 24 month interval) review and update as necessary. This standards document is a "***living document***".

2. INTEROPERABILITY AND STANDARDS

The recommendations outlined in this section are an incremental approach to adopting standards, implementation specifications, and criteria to enhance the interoperability, functionality, utility, and security of health information technology and to support its widespread adoption. It is to be kept in mind that these standards should be flexible and modifiable to adapt to the demographic and resource variance observed in a large and developing country like India.

It is important to recognize that interoperability and standardization can occur at many different levels. To achieve interoperability, information models would need to be harmonized into a consistent representation.

In other cases, organizations may use the same information model, but use different vocabularies or code sets (for example, Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) or ICD10-CM within those information models. To achieve interoperability at this level, standardizing vocabularies, or mapping between different vocabularies (using tools like Unified Medical Language System (UMLS)) may be necessary. For some levels, (such as the network transport protocol), an industry standard that is widely used (e.g. TCP/IP – TransmissionControl Protocol and Internet Protocol) will likely be the most appropriate. Ultimately, to achieve semantic interoperability, it is anticipated that multiple layers – network transportation protocols, data and services descriptions, information models, and vocabularies and code sets – will need to be standardized and/or harmonized to produce an inclusive, consistent representation of the interoperability requirements.

It is further anticipated that using a harmonization process will integrate different representations of health care information into a consistent representation and maintain and update that consistent representation over time. For an information model, this process could include merging related concepts, adding new concepts, and mapping concepts from one representation of health care information to another. Similar processes to support standardization of data and services descriptions and vocabularies and codes sets may also be needed.

It is also recognized that a sustainable and incremental approach to the adoption of standards will require processes for harmonizing both current and future standards. This will allow the incremental updating of the initial set of standards, implementation specifications, and certification criteria and provide a framework to maintain them. The decision to adopt such updates will be informed and guided by recommendations from an appropriate authority akin to a National Health Information Authority.

Goals

- Promote interoperability and where necessary be specific about certain content exchange and vocabulary standards to establish a path forward toward semantic interoperability
- Support the evolution and timely maintenance of adopted standards
- Promote technical innovation using adopted standards
- Encourage participation and adoption by all vendors and stakeholders
- Keep implementation costs as low as reasonably possible
- Consider best practices, experiences, policies and frameworks
- To the extent possible, adopt standards that are modular and not interdependent.

53

Categories for adoption of standards

Vocabulary Standards

(i.e., standardized nomenclatures and code sets used to describe clinical problems and procedures, medications, and allergies)

This is to be achieved through the extensive use of Controlled Medical Vocabularies (CMV) that is detailed as follows:

a) Logical Observation Identifiers Names and Codes (LOINC®): A universal code system for identifying laboratory and clinical observations. From serum levels of hepatitis B surface antigen to diastolic blood pressure, LOINC has standardized terms for all kinds of observations and measurements that enable exchange and aggregation of electronic health data from many independent systems. It was developed to provide a definitive standard for identifying clinical information in electronic reports. The LOINC database provides a set of universal names and ID codes for identifying laboratory and clinical test results in the context of existing HL7, ASTM E1238, and CEN TC251 observation report messages. One of the main goals of LOINC is to facilitate the exchange and pooling of results for clinical care, outcomes management, and research. LOINC codes are intended to identify the test result or clinical observation. Other fields in the message can transmit the identity of the source laboratory and special details about the sample. It has since been reported that the Regenstrief Institute Inc. and the International Health Terminology Standards Development Organisation (IHTSDO) have signed a long-term agreement to begin cooperative work linking their leading global health care terminologies: Logical Observation Identifiers Names and Codes, or LOINC, and SNOMED Clinical Terms.

b) International Classification of Diseases (ICD10): The ICD is the international standard diagnostic classification for all general epidemiological, many health management purposes and clinical use.

c) Systematized Nomenclature of Medicine--Clinical Terms (SNOMED-CT): is a comprehensive clinical terminology, originally created by the College of American Pathologists (CAP) and owned, maintained, and distributed by the International Health Terminology Standards Development Organization (IHTSDO), a non-for-profit association in Denmark.

d) Current Procedural Terminology, 4th Edition (CPT 4): The CPT-4 is a uniform coding system consisting of descriptive terms and identifying codes that are used primarily to identify medical services and procedures furnished by physicians and other health care professionals.

e) ATC – Anatomic Therapeutic Chemical Classification of Drugs: is used for the classification of drugs. It is controlled by the WHO Collaborating Centre for Drug Statistics Methodology (WHOCC), and was first published in 1976. This pharmaceutical coding system divides drugs into different groups according to the organ or system on which they act and/or their therapeutic and chemical characteristics. Each bottom-level ATC code stands for a pharmaceutically used substance in a single indication (or use). This means that one drug can have more than one code: acetylsalicylic acid (aspirin), for example, has A01AD05 as a drug for local oral treatment, B01AC06 as a platelet inhibitor, and N02BA01 as an analgesic and antipyretic. On the other hand, several different brands share the same code if they have the same active substance and indications.

Content Exchange Standards

(i.e., standards used to share clinical information such as clinical summaries, prescriptions, and structured electronic documents)

a) Health Level Seven (HL7) Clinical Document Architecture: is an XML-based mark-up standard intended to specify the encoding, structure and semantics of clinical documents for exchange. CDA

(52)

is being used also in electronic health records projects to provide a standard format for entry, retrieval and storage of health information

b) HL7 2.5.1: defines a series of electronic messages to support administrative, logistical, financial as well as clinical processes and mostly uses a textual, non-XML encoding syntax based on delimiters. HL7 v2.x has allowed for the interoperability between electronic Patient Administration Systems (PAS), Electronic Practice Management (EPM) systems, Laboratory Information Systems (LIS), Dietary, Pharmacy and Billing systems as well as Electronic Medical Record (EMR) or Electronic Health Record (EHR) systems

c) Continuity of Care Record (CCR) is a health record standard specification developed jointly by ASTM International, the Massachusetts Medical Society (MMS), the Healthcare Information and Management Systems Society (HIMSS), the American Academy of Family Physicians (AAFP), the American Academy of Pediatrics (AAP), and other health informatics vendors. It is a core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounters. It provides a means for one healthcare practitioner, system, or setting to aggregate all of the pertinent data about a patient and forward it to another practitioner, system, or setting to support the continuity of care. The primary use case for the CCR is to provide a snapshot in time containing the pertinent clinical, demographic, and administrative data for a specific patient. To ensure interchange ability of electronic CCRs, this specification specifies XML coding that is required when the CCR is created in a structured electronic format. Conditions of security and privacy for a CCR instance must be established in a way that allows only properly authenticated and authorized access to the CCR document instance or its elements. The CCR consists of three core components: the CCR Header, the CCR Body, and the CCR Footer.

d) Digital Imaging and Communications in Medicine (DICOM): The DICOM Standards Committee exists to create and maintain international standards for communication of biomedical diagnostic and therapeutic information in disciplines that use digital images and associated data. The goals of DICOM are to achieve compatibility and to improve workflow efficiency between imaging systems and other information systems in healthcare environments worldwide. DICOM currently defines an upper layer protocol (ULP) that is used over TCP/IP (independent of the physical network), messages, services, information objects and an association negotiation mechanism. These definitions ensure that any two implementations of a compatible set of services and information objects can effectively communicate.

Clinical Standards

Clinical standards are health information standards to capture a patient's health information in a more coherent manner. This health information can include all or part thereof as relevant of the following:

- The illness a patient is suffering from
- The physician's observation of the patient's illness
- The diagnostic tests that need to be carried out to ascertain the patient's illness and to give the patient better treatment
- The results of the diagnostic tests
- The kind of treatment to be given to the patient
- The way the treatment should be given to the patient

57

RECOMMENDED HEALTHCARE IT STANDARDS (FOR INDIA)

Name	Class	Comments
Phase 1		
UHID	Unique Health Identifier – to act as Patient Identifier	UID as a unique (primary or secondary) patient identifier. The UID should be used to identify a particular patient across all organizations (and their EMR systems); Aadhar number is recommended for use in EMR as either the primary or secondary, where the primary is an internal unique health identifier used by the healthcare provider organisation.
CCD (HL7/ASTM)	Clinical Data for Inter Department documents (the CDA CCD)	Likely to be used for exchanging the clinical documentation between two EHR solutions both within an organisation and outside
ATC Pharmacologic-Therapeutic Classification Indian Drugs – MIMS/CIMS from CMPmedica	Medicines	Needs to be researched as there is no universal drug reference database. The WHO Drug Dictionary ATC – anatomic therapeutic classification – may be a good choice to begin with
LOINC	Clinical Laboratory Observations	Published and maintained by the Regenstrief Institute, USA, this is a universally accepted code for laboratory observations
HL7 V2.x	Messaging	V2.3 or above
HL7 V3.0 RIM	Reference Information Model	Intermediate recommendation; to be replaced with HL7 FHIR when it is accepted by BIS/HL7-India
DICOM PS3.0	Medical Images	Revision 2004
ISO 18308	Reference EHR Requirements Specification	The latest version
CEN / TC 251 EN 13606	Reference Model & Archetypes	The latest version
SNOMED-CT	Clinical Terminology	Provide comprehensive clinical granularity, used to capture problem list, allergies, diagnosis, procedures etc. – will immensely aid in clinical analytics, clinical decision support systems, automated clinical care pathway management systems, support evidence based practice, etc.

WHO ICD 10	Disease classification	WHO is actively working with IHTSDO to converge SNOMED-CT with ICD
WHO – PCS	Procedure coding system	
WHO – ICF	International classification of functioning, disability & health	
Phase 2		
DSM	Psychiatric conditions	Diagnostic & statistical manual of mental disorders
NIC/NOC/NANDA	Nursing interventions classification	This is optional
CDT 2, US	Dental Procedures	This is optional
ICTM	International Classification of Traditional Medicine	Ayurveda, Yoga, Unani, Siddha, Homeopathy systems of medicine as distinct from the allopathic (Western) system of medicine

Table 1: HCIT Standards (applicable in India)

For all recommended standards, the most recent release of the standard by BIS (or source body where BIS has not specified) as on date of enforcement of these recommendation are to be used unless specifically mentioned here.

Related Issues

- Unique Identification
- Interoperability / Sharing
- Integrated systems require consistent use of standards in e.g. medical terminologies and high quality data to support information sharing across wide networks
- Ethical, legal and technical issues linked to the accuracy, security confidentiality and access rights.
- Common record architectures, structures
- Clinical information standards and communications protocols

International Standards Organization and Bureau of Indian Standards

India is a voting member of ISO's Technical Committee 215 for Health Informatics. As such, the country is duty-bound to adopt and enforce all adopted standards that she had voted in favour.

The following list of such ISO standards and technical specifications that will need to be referred to when designing EHR Systems for India. Needless to say, this list is very dynamic as older standards get subsequently replaced by newer ones.

Consequently, it is advisable to refer to BIS website to source documents pertaining to Health Informatics Sectional Committee – MHD 17 for the latest standards currently in force.

These documents must be seen to be as additional reference materials. Thus, wherever additional information is required for proper designing of an EHR/EMR System, these documents may be used for reference purposes to derive additional guidelines.

Please note:

- *Wherever the provisions of the EHR Standards are in conflict with any other, these EHR Standards will always prevail.*
- *The following list is indicative and representive and not comprehensive and definitive.*

Standards (the latest version) that are to additionally be incorporated:

S. No.	Doc No	Description
1	ISO 21090: 2011	Harmonized data types for information interchange
2	ISO 12967: 2009	Health Informatics Service Architecture (Parts 1 - 3)
3	ISO TS 22220: 2011	Identification of subjects of health care
4	ISO TS 27527: 2010	Provider identification
5	ISO TS 14265	Classification of purposes for processing personal health information
6	ISO 13940	System of concepts to support continuity of care
7	ISO 13972	Detailed Clinical Models
8	ISO 20301:2006	Health informatics-Health Cards-General Characteristics
9	ISO DIS 22857	Health informatics - Guidelines on data protection to facilitate trans-border flows of personal health data
10	ISO/TS 22220:2008(E)	Health informatics — Identification of subjects of health care
11	ISO 13606-1	Health informatics — Electronic health record communication — Part 1:Reference model
12	ISO DIS 13119	Health informatics — Clinical knowledge resources — Metadata
13	ISO DIS 22600-1	Health informatics — Privilege management and access control — Part 1: Overview and policy management
14	ISO DIS 22600-2	Health informatics — Privilege management and access control — Part 2: Formal models
15	ISO DIS 22600-3	Health informatics — Privilege management and access control — Part 3: Implementations
16	ISO DTS 14441	Health informatics — Security and privacy requirements of EHR systems for use in conformity assessment
17	ISO FDIS 17090-1	Health informatics — Public key infrastructure — Part 1: Overview of digital certificate services
18	ISO FDIS 21549-1	Health informatics — Patient healthcard data — Part 1: General structure
19	ISO DIS 13940	Health informatics — System of concepts to support continuity of care

Table 2: Additional ISO Standards

- *Standards that have already been taken into consideration within this standards document*:

S. No.	Doc No	Description
1	ISO DIS 1828	Health informatics — Categorial structure for classifications and coding systems of surgical procedures
2	ISO DIS 11616	Health informatics — Identification of medicinal products — Data elements and structures for unique identification and exchange of regulated pharmaceutical product information
3	ISO DIS 11615	Health informatics — Identification of medicinal products — Data elements and structures for unique identification and exchange of regulated medicinal product information
4	ISO DIS 11240	Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement
5	ISO DIS 11238	Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances
6	ISO FDIS 21090	Health informatics — Harmonized data types for information interchange
7	ISO DIS 27789.2	Health informatics — Audit trails for electronic health records
8	ISO 27932: 2009	HL7 Clinical Document Architecture, Release 2
9	ISO TS 22600: 2006	Privilege management and access control (Parts 1-3)
10	ISO 27799:2008:	Health informatics -- Information security management in health using ISO/IEC 27002
11	ISO 17115:2007	Health Informatics-Vocabulary for terminological systems
12	ISO 17115:2007	Health Informatics-Vocabulary for terminological systems
13	ISO 12052:2006	Health Informatics-Digital Imaging and Communication in medicine (DICOM) including work flow and data management
14	ISO CD 17583	Health informatics -- Terminology constraints for coded data elements expressed in ISO Harmonized Data Types used in healthcare information interchange
15	ISO/TS 22220:2008(E)	Health informatics — Identification of subjects of health care
16	ISO DTS 14441	Health informatics — Security and privacy requirements of EHR systems for use in conformity assessment

Table 3: ISO Standards Already Considered

Reference Model[1]

openEHR (www.openehr.org) is a virtual community working on interoperability and computability in e-health. Its main focus is electronic patient records (EHRs) and systems.

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[1] Information as available from openEHR website

The openEHR Foundation has published a set of specifications defining a health information reference model, a language for building 'clinical models', or archetypes, which are separate from the software, and a query language.

The architecture is designed to make use of external health terminologies, such as SNOMED CT, LOINC and ICDx. Components and systems conforming to openEHR are 'open' in terms of data (they obey the published openEHR XML Schemas), models (they are driven by archetypes, written in the published ADL formalism) and APIs. They share the key openEHR innovation of adaptability, due to the archetypes being external to the software, and significant parts of the software being machine-derived from the archetypes.

The essential outcome is systems and tools for computing with health information at a semantic level, thus enabling true analytic functions like decision support, and research querying.

Being an ISO standard, ISVs are strongly encouraged to be guided by the contents in their system design.

Discharge/Treatment Summary Format

The format for Medical Records as specified by Medical Council of India under regulation 3.1 of ethics, will need to be followed whenever any discharge or treatment summary is prepared. The specified format is provided in Chapter 11 of this document for ready reference. ISVs should additionally refer to available openEHR archetypes for the same.

Interfacing with Personal Healthcare and Medical Devices

Where not covered under relevant data exchange standards, it is recommended that IEEE 11073 health informatics standards and related ISO standards for medical devices be followed as appropriate whenever any personal healthcare/medical device is interfaced with the EHR System for the purpose of clinical data exchange, retrieval, storage, etc.

VARIOUIS ORGANISATIONS AND THEIR RECOMMENDED HEALTHCARE INFORMATICS STANDARDS

Organization	**Standards**
Ministry of Communications and Information Technology, Government of India	➢ Information Technology Infrastructure for Health (ITIH) framework ➢ Recommendations on Guidelines, Standards & Practices for Telemedicine in India
National Knowledge Commission	➢ Indian health information network development (iHIND) recommendations from the National Knowledge
International Organization for Standardization (ISO)	Requirements for Electronic Health Record Architecture (**ISO / TS 18308**)
European Committee for Standardization (CEN)	CEN / TC 251 **EN 13606**
American Society for Testing & Materials (ASTM)	Continuity of Care Record (**CCR**)

46

Health Level 7 (HL7)	➢ HL7 v2.x ➢ HL7 v3 ➢ CDA – 2 ➢ FHIR (Fast Health Interoperable Resources) – the newest version; easy upgrade from v2.x to FHIR ➢ EHR - System Functional Model
HL7 & ASTM Collaboration	Continuity of Care Document (**CCD**)
National Electrical Manufacturer's Association (NEMA)	Digital Imaging and Communications in Medicine (**DICOM PS 3.0 2004** onwards)

Table 4: Organisations and their recommended Health Informatics Standards

95

3. GUIDELINES

Hardware

- The IT hardware used should meet (and preferably be better than) the optimal requirement given by the software (to be) used.
- The medical and IT hardware used must meet the relevant applicable specifications from BIS, NEMA, ISO, CE, RoHS, EnergyStar, apart from Medical and IT standards for the equipment.
- A backup or data preservation mechanism should be considered. Data capacity should be planned to meet the storage requirement as per the mandated rule/law.
- System redundancy at various levels (disk, power, network, etc.) should be planned to meet the organizational system availability requirement.
- Network and data security should be planned, implemented, and periodically audited. Please see section on Security and Privacy for requirements and functions to be supported and implemented.
- Hardware should be checked periodically for correctness and completeness of operation expected from them. An appropriate maintenance cycle should be planned and followed.
- Planned and expected Capacity and Quality requirement of the organization should be met by the hardware used. Periodic updates and upgrades should be carried out to meet the requirements.

Networking and Connectivity

- Should be able to harness any telecommunications-related connectivity like the Internet, LAN, WAN, WAP, CDMA, GSM or even Cloud Computing that will permit the various EMRs of an individual to be integrated into a single lifelong electronic health record
- As far as practical and affordable, the connectivity medium chosen should be reliable and fast enough to sustain a secure data exchange for the period expected for transaction of records and data. The speed of the connectivity medium should be chosen from among available options so as to provide an acceptable user experience and not cause software/system fault due to delays/noise/failure.
- Should be able to ensure that data exchange is performed in a secure manner to ensure data validity and non-repudiability
- The data exchange must further ensure that data integrity is maintained at all times

Software Standards

The software should

- Conform to the specified standards
- Satisfy specified requirements
- Be Interoperable
- Should be able to ensure role based access control at all times
- Should be able to support privacy, secrecy and audit trail
- Possess advanced search, merge, and demerge functionality to ensure that duplicates are robustly resolved
- Should be able to support conception-to-current health records of a person
- Should be able to support digital archiving and retrieval of health records after the death of a person for the total duration as specified by Government of India from time to time

(49)

- Should be able to construct a health/clinical summary based on available records from the very first visit to current
- Should be able to support for rapid data capture-storage-retrieval-display of data
- Should be able to ensure user authentication and authorisation

Proposed Mobile Health Record

As patients move around the healthcare system there is a need to carry essential information to ensure quality healthcare which will give their treating clinician basic information viz., health condition, drug/allergy information etc. CCR standard XML file format, with demographics, insurance info, problem list/diagnoses, medications, allergy and alerts, vital signs, and lab results, consultation reports, hospital discharge and operative reports and investigative and diagnostic results (e.g. ECG reports, tread mill test results, biochemistry results, histopathological findings, ultrasound findings, etc.) kept current and accurate by a person's healthcare team (nurses, doctors and pharmacists) which includes the patient.

Conformance to m-governance guidelines of DEITY is imperative(http://www.deity.gov.in/content/framework-mobile-governance).

43

4. DATA OWNERSHIP OF EHR

The Ethical, Legal, Social Issues (ELSI) guidelines for Electronic Health Record (EHR) are recommended as follows.

For the purposes of these recommendations, the term "**privacy**" shall mean that only those person or person(s) including organisations duly authorized by the patient may view the recorded data or part thereof. The term "**security**" shall mean thatall recorded personally identifiable data will at all times be protected from any unauthorized access, particularly during transport (e.g. from healthcare provider to provider, healthcare provider to patient). The term "**trust**" shall mean thatperson, persons or organisations (doctors, hospitals, patients) are those who they claim they are.

The following approaches are to be adopted wherever applicable:

- Privacy would refer to authorization by the owner of the data (the patient)
- Security would have as components both public and private key encryption; the encryptions used in transit and at rest need to be through a different methodology.
- Trust would be accepted whenever a trusted third party confirms identify

Protected health information (PHI) would refer to any individually identifiable information whether oral or recorded in any form or medium that (1) is created, or received by a stakeholder; and (2) relates to past, present, or future physical or mental health conditions of an individual; the provision of health care to the individual; or past, present, or future payment for health care to an individual.

Electronic protected health information (ePHI) would refer to any protected health information (PHI) that is created, stored, transmitted, or received electronically. Electronic protected health information includes any medium used to store, transmit, or receive PHI electronically.

The following and any future technologies used for accessing, transmitting, or receiving PHI electronically are covered:

- Media containing data at rest (data storage)
    - Personal computers with internal hard drives used at work, home, or traveling
    - External portable hard drives, including iPods and similar devices
    - Magnetic tape
    - Removable storage devices, such as USB memory sticks, CDs, DVDs, and floppy disks
    - PDAs and smartphones
- Data in transit, via wireless, Ethernet, modem, DSL, or cable network connections
    - Email
    - File transfer

For data ownership, a distinction is to be made between

a. The physical or electronic records, which are owned by the healthcare provider. These are held in trust on behalf of the patient, and

b. The contained data which are the sensitive personal data of the patient is owned by the patient himself/herself.

c. The healthcare provider will have the privilege to change/append/modify any record in relation to the health care of the patient as necessary with a complete documented trail of such change. No alteration of the previously saved data will be permitted.No update or update like command shall be utilised by the system to store a record or part thereof. A new record will be created with the unaltered parts of the existing record. The changed/appended/modified data will replace the relevant parts of that record. This record shall then be stored and marked as active while rendering the previous version or versions of the same record marked inactive. The data will thus be immutable. A strict audit trail shall be maintained of all activities at all times that may be suitably reviewed by an appropriate authority like auditor, legal representatives of the patient, the patient, healthcare provider, privacy officer, court appointed/authorised person, etc.

d. The medium of storage or transmission of such electronic health record will be owned by the healthcare provider.

e. The "sensitive personal information (SPI) and personal information (PI)" of the patient is owned by the patient themselves. Refer to IT Act 2000 for the definition of SPI and PI.

f. Sensitive Data: As per the Information Technology Act 2000, Data Privacy Rules, refer to 'sensitive personal data or information' (Sensitive Data) as the subject of protection, but also refer, with respect to certain obligations, to 'personal information'. Sensitive Data is defined as a subset of 'personal information'. Sensitive Data is defined as personal information that relates to:

    i. Passwords;
    ii. Financial information such as bank account or credit card or debit card or other payment instrument details;
    iii. Physical, psychological and mental health condition;
    iv. Sexual orientation;
    v. Medical/clinical records and history;
    vi. Biometric information;
    vii. Any detail relating to (1) – (6) above received by the body corporate for provision of services; or
    viii. Any information relating to (1) – (7) that is received, stored or processed by the body corporate under a lawful contract or otherwise

Data access and confidentiality would refer to:

a. Regulations are to be enforced to ensure confidentiality of the recorded patient/health data and the patient should have a control over this.

b. Patients will have the sufficient privileges to inspect and view their health records without any time limit. Patient's privileges to amend data shall be limited to correction of errors in the recorded patient/health details. This shall need to be performed through a recorded request made to the healthcare provider within a period of 30 days from the date of discharge in all inpatient care settings or 30 days from the date of clinical encounter in outpatient care settings. An audit of all such changes shall be strictly maintained. Both the request and audit trail records shall be maintained within the system. Patients will have the privileges to restrict access to and disclosure of individually identifiable hea[illegible] information.

c. All recorded data will be available to care providers on an 'as required on demand' basis

d. Minimum data standards

Disclosure of information would be applicable as follows:

a. For use for treatment, payments and other healthcare operations: In all such cases, a general consent must be taken from the patient or next of kin, etc. as defined by applicable laws by MCI[2].

b. Fair use for non-routine and most non-health care purposes: a specific consent must be taken from the patient; format as defined by MCI.

c. Certain national priority activities, including notifiable/communicable diseases, will be specified for which health information may be disclosed to appropriate authority as mandated by law without the patient's prior authorization

Responsibilities of any healthcare provider would include:

a. Protect and secure the stored health information, as per the guidelines specified in this document (chapter on Data privacy and security).

b. While providing patient information, remove patient identifying information (as provided in Table 1), if it is not necessary to be provided

c. Will ensure that there are appropriate means of informing the patient of policies relating to his/her rights to health record privacy

d. Document all its privacy policies and ensure that they are implemented and followed. This will include:

    i. Develop internal privacy policies

    ii. Designate a privacy officer (preferably external, may be internal) who will be responsible for implementing privacy policies, audit and quality assurance

    iii. Provide privacy training to all its staff

Patient will have the privilege to appoint a personal representative to carry out the activities detailed below.

a. Patients will have the privilege to ask for a copy of their health records held by a healthcare organization.

b. Patients will have the privilege to request a healthcare organization that holds their health records, to withhold specific information that he/she does not want disclosed to other organizations or individuals.

c. Patient can demand information from a healthcare provider on the details of disclosures performed on the patients health records.

Instances where denial of information will apply are as follows:

Healthcare provider will be able to deny information to a patient or representative or third party, in contravention of normal regulations, if in the opinion of a licensed healthcare

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[2] http://www.mciindia.org/rules-and-regulation/Code%20of%20Medical%20Ethics%20Regulations.pdf

(40)

professional the release of information would endanger the life or safety of the patients and others. This will include but not be limited to as follows:

d. Information obtained from an anonymous source under a promise of confidentiality.

e. Psychotherapy notes.

f. Information compiled for civil, criminal or administrative action.

Instances where use and disclosure without individual authorization will be possible are as follows:

Disclosures can be performed without individual authorization in the following situations.

- **With Identifiers,** on production of court order
- However, as far as possible, and where appropriate, the data so provided should be anonymised to remove information that will allow identification of the patient. (Removing identifiers as indicated in the Patient Identifying Information Table below)

Digital signatures are to be used to prevent non-repudiation (establishing authenticity of author of the document) and trust by the recipient.

Follow **e-Pramaan National e-Authentication service** offered by DeitY, Govt. Of India

http://epramaan.gov.in/

Reference Framework for e-authentication – ePramaan

http://egovstandards.gov.in/policy/framework-document-for-e-authentication-epramaan

Reference Guidelines for Digital Signatures, available at
http://egovstandards.gov.in/guidelines/Guidelines%20for%20Digital-signature/view

Additional Reference Guidelines for Information Security, available at
http://egovstandards.gov.in/guidelines/guidelines-for-information-security/view

Electronic Health Records Preservation

Preservation of health records assume significant importance in view of the fact that an electronic health record of a person is an aggregation of all electronic medical records of the person from the very first entry till date. Hence, all records must compulsorily be preserved and not destroyed during the life-time of the person, ever.

The digital records must be preserved till such time according to the prevalent law of the land.

It is however preferred and ISVs are strongly encouraged to ensure that the records are never be destroyed or removed permanently. The health of the blood relatives and natural descendants of the person can be strongly influenced by the health of the person and on-demand access to these may prove to be hugely useful in the maintenance of the health of the the relations.

Furthermore, analysis of health data of all persons is expected to greatly benefit in the understanding of health, disease processes and the amelioration therof.

With rapid decline in costs of data archiving coupled with the ability to store more and more data that may be readily accessible, continued maintenance of such data is not expected to lead to any big impact on the overall system maintenance and use.

Patient Identifying Information

Data are "individually identifiable" if they include any of the under mentioned identifiers for an individual or for the individual's employer or family member, or if the provider or researcher is aware that the information could be used, either alone or in combination with other information, to identify an individual. These identifiers are as follows:

1. Name
2. Address (all geographic subdivisions smaller than street address, , and PIN code)
3. All elements (except years) of dates related to an individual (including birth date, date of death,
4. Telephone and/or Fax numbers
5. Email address
6. Medical record number
7. Health plan beneficiary number
8. Bank Account and/or Credit Card Number
9. Certificate/license number
10. Any vehicle or other any other device identifier or serial numbers
11. PAN number
12. Passport number
13. ADHAAR number
14. Voter ID card
15. Fingerprints/Biometrics
16. Voice recordings that are non-clinical in nature
17. Photographic images and that possibly can individually identify the person
18. Any other unique identifying number, characteristic, or code

Table 5: Patient Identifying Information

Applicable legislation details: The existing Indian laws, including but not limited to IT Act 2000 and as amended from time to time will prevail at all times (http://deity.gov.in/content/information-technology-act-2000)

38

5. DATA PRIVACY & SECURITY

Security of Electronic Health Information:

The Privacy Standards and the Security Standards are necessarily linked. Any health record system requires safeguards to ensure the data is available when needed and that information is not used, disclosed, accessed, altered, or deleted inappropriately while being stored or transmitted. The Security Standards work together with the Privacy Standards to establish appropriate controls and protections. Health sector entities that are required to comply with the Privacy Standards also must comply with the Security Standards.

Organizations must consider several factors when adopting security measures. How a healthcare provider satisfies the security requirements and which technology it decides to use are business decisions left to the individual organization. In deciding what security measures to adopt, an organization must consider its size, complexity, and capabilities; it's technical infrastructure, hardware, and software security capabilities; the cost of particular security measures; and the probability and degree of the potential risks to the e-PHI it stores and transmits.

Standards

Purpose of the Security Standards

The Security Standards require healthcare providers to implement reasonable and appropriate **administrative**, **physical**, and **technical safeguards** to

- Ensure the confidentiality, integrity, and availability of all the e-PHI they create, transmit, receive, or maintain
- Protect against reasonably anticipated threats or hazards to the security or integrity of their e-PHI
- Protect against uses or disclosures of the e-PHI that are not required or permitted under the Privacy Standards
- Ensure their workforce will comply with their security policies and procedures

Technical Standards

To protect the e-PHI handles by a healthcare provider, the provider must implement technical safeguards as part of its security plan. Technical safeguards refer to using technology to protect e-PHI by controlling access to it. Therefore, they must address the following standards focusing on the following. It is worth noting that they will need to use an EHR solution that is able to successfully and robustly demonstrate the possession and working of these functionalities.

Access control: The solution must assign a unique name and/or number for identifying and tracking user identity and establish controls that permit only authorized users to access electronic health information. In cases of emergency where access controls need to be suspended in order to save a live, authorized users (who are authorized for emergency situations) will be permitted to have unfettered access electronic health information for the duration of the emergency with the access remaining in force during the validity of the emergency situation.

Access Privileges: Ideally only clinical care providers should have access rights to a person's clinical records. However, different institutional care providers have widely varying access privileges specified that are institution-specific. No country-wide standards can be specified for this at least at this point in time.

Automatic log-off: An electronic session after a predetermined time of inactivity must be forcibly terminated. To log in back, the user will have to initiate a new log in session. However, for the sake of ergonomics, it is recommended that the unsaved state of the system at the time of automatic log-off be saved and presented back to the user for further action. This should be a user-specific feature.

Audit log:

- All actions related to electronic health information in accordance with the standard specified in this document including viewing should be recorded.
- Based on user-defined events must be provided.
- All or a specified set of recorded information upon request or at a set period of time must be electronically displayed and printed.

Integrity:

- **During data transit** the fact that the electronic health information has not been altered in transit in accordance with the standard specified in this document must be verifiable.
- **Detection of events** – all alterations and deletions of electronic health information and audit logs, in accordance with the standard specified in this document must be detected.

Authentication:

- **Locally within the system** the fact that a person or entity seeking access to electronic health information is the one claimed and is authorized to access such information must be verifiable.
- **Across the network**, however extensive it might be –that a person or entity seeking access to electronic health information across a network is the one claimed and is authorized to access such information in accordance with the standard specified in this document must be verifiable.

Encryption:

- Generally, all electronic health information must be encrypted and decrypted as necessary according to user defined preferences in accordance with the best available encryption key strength.
- During data exchange all electronic health information must be suitably encrypted and decrypted when exchanged in accordance with an encrypted and integrity protected link.
- All actions related to electronic health information must be recorded with the date, time, patient identification, and user identification whenever any electronic health information is created, modified, deleted, or printed; and an indication of which action(s) took place must also be recorded.
- Appropriate verification that electronic health information has not been altered in transit shall be possible at any point in time. A secure hashing algorithm must be used to verify that electronic health information has not been altered in transit and it is recommended that the secure hash algorithm (SHA) used must be SHA-1 or higher.
- A cross-enterprise secure transaction that contains sufficient identity information such that the receiver can make access control decisions and produce detailed and accurate security audit trails must be used within the system.

36

Administrative Safeguards Standards

The Administrative Safeguards require healthcare providers to develop and implement a security management process that includes policies and procedures that address the full range of their security vulnerabilities. Being administrative in nature, these need to be internally designed and developed as SOP that must be published for all users to see and adhere to. Conformance to adherence may be delegated to the Privacy Officer detailed in the Data Ownership chapter above. To comply with the Administrative Safeguards, a healthcare provider must implement the following standards.

- The security management process standard, to prevent security violations;
- Assigned security responsibility, to identify a security officer;
- Workforce security, to determine e-PHI user access privileges;
- Information access management, to authorize access to e-PHI;
- Security awareness training, to train staff members in security awareness;
- Security incident procedures, to handle security incidents;
- Contingency plan, to protect e-PHI during an unexpected event; and
- Evaluation, to evaluate an organization's security safeguards.

Physical Safeguards Standards

Physical safeguards are security measures to protect a healthcare provider’s electronic information systems, related equipment, and the buildings housing the systems from natural and environmental hazards, and unauthorized intrusion. Covered entities must fulfill the following four standards. However, since most of the implementation specifications in this category are addressable, healthcare providers will have considerable flexibility in how to comply with the requirements as long as these are internally designed and developed as SOP and published for all users to see and adhere to. Conformance to adherence may be delegated to the Privacy Officer detailed in the Data Ownership chapter above.

The required physical standards are:

- The facility access control standard, to limit actual physical access to electronic information systems and the facilities where they're located;
- The workstation use standard, to control the physical attributes of a specific workstation or group of workstations, to maximize security;
- The workstation security standard, to implement physical safeguards to deter the unauthorized access of a workstation; and
- The device and media controls standard, to control the movement of any electronic media containing e-PHI from or within the facility.

6. REFERENCES

(1) Final Recommendation, Framework for Information Technology Infrastructure for Health in India (ITIHI), Volumes I & II, DIT, MCIT, Govt. of India
(2) Recommendations on Guidelines, Standards & Practices for Telemedicine in India, DIT, MCIT, Govt. of India
(3) HIM Principles in Health Information Exchange (Practice Brief)
(4) 2006 HIMSS RHIO Definition Workgroup
(5) http://healthit.hhs.gov/portal/server.pt?open=512&objID=2996&mode=2 (see below)
(6) Institute of Medicine (2000). "To Err Is Human: Building a Safer Health System (2000)". The National Academies Press. http://fermat.nap.edu/catalog/9728.html#toc. Retrieved 2006-06-20.
(7) Charatan, Fred (2000). "Clinton acts to reduce medical mistakes". BMJ Publishing Group.http://bmj.bmjjournals.com/cgi/content/full/320/7235/597?ijkey=190e9b6dd6e8fec4ca3c2e353f290efb8237b334&keytype2=tf_ipsecsha. Retrieved 2006-03-17
(8) Department of Health and Human Services, USA, USA Billing Code: 4150-45
(9) HIPAA Laws: Privacy and Security 45 CFR 142
(10) EHR Meaningful Use
(11) CCR – http://www.astm.org/Standards/E2369.htm
(12) ATC – http://www.whocc.no/atc_ddd_index/

7. ANNEXURE: EHR MINIMUM DATA SET (MDS)

The following MDS is a reference data model. In order to kick-start EHR system implementation, a reference c
However, ISVs must follow the data model/structure as provided in the applicable standard for the purpose.

Vendors are free and indeed encouraged to opt for additional data to satisfy additional and the unmet need
principally the patients and the clinical care providers.

Data Item	Data Type	Data Length	Format/Values	Status	Additi
UHID	Numeric	12	As per Aadhar Specifications	Mandatory if no other concomitant ID is used in the system, else optional	Only th that to patient demer **Adhaa will ne district the pat father' to uniq**
Alternate UHID	Any	Any	As per institution/vendor's specifications	Mandatory if no other concomitant ID is used in the system, else optional	Any otl includi issued govern long as

Patient Name	As specified	As specified	To be split into First Name, Middle Name and Last (Family) Name	Mandatory	MDDS (http:/, rdsand data-st Demog downlc for pat the per meta d applica
Patient Date of Birth	Date	As specified		Mandatory in Inpatients settings, Optional in others	As spec
Patient Age	Numeric	Fixed	999,99,999 no preceding zero [years, months, days]	Mandatory	Age is if date once tl client "age" the p availab approx that th day of the ent The re clearly approx patient month

Patient Gender	Alphanumeric	1	To be shortened to one byte as M, F, I or N for Male, Female, Indeterminate, Not Stated/Inadequately Described. Systems should translate and show the full form on user screens	Mandatory	The val 22220: Identifi care (N specifi se)
Patient Occupation	As specified	As specified		Mandatory	It is rec followe
Patient Address Type	Alphanumeric	9	Current/Permanent /Previous	Mandatory	
Patient Address Line 1	As specified	As specified		Mandatory	It is rec followe
Patient Address Line 2	As specified	As specified		Optional	It is rec followe
Patient City/Town/Village/Police Station	As specified	As specified		Mandatory	It is rec followe
Patient District	As specified	As specified		Mandatory	It is rec followe
Patient State	As specified	As specified		Mandatory	It is rec followe Alterna be use
Patient Pin Code	As specified	As specified		Optional	It is rec followe

Patient Country Code	As specified	As specified	As per ISO Country Codes	Mandatory	ISO 31 alpha-
Patient Phone Type	Alphanumeric	20	Landline/Mobile/PP-Landline/Neighbour Landline/Relation Landline /Neighbour Mobile/Relation Mobile	Optional	
Patient Phone Number	Alphanumeric	16	(099)9999999999	Optional	
Patient Email ID	Alphanumeric	255	Must contain '@' and "." at appropriate positions	Optional	
Emergency Contact Person Name	As specified	As specified		Optional	It is rec followe
Emergency Contact Person Relationship	Alphanumeric	9	Spouse/Parent/Child/Partner/Cousin/Friend/Neighbour/Other	Mandatory, if used, else Optional	
Emergency Contact Person Address Type	Alphanumeric	9	Current/Permanent /Previous	Mandatory, if used, else Optional	

Emergency Contact Person Address Line 1	As specified	As specified		Mandatory, if used, else Optional	It is rec followe
Emergency Contact Person Address Line 1	As specified	As specified		Mandatory, if used, else Optional	It is rec followe
Emergency Contact Person Address Line 2	As specified	As specified		Optional	It is rec followe
Emergency Contact Person City/Town/Village/ Police Station	As specified	As specified		Mandatory, if used, else Optional	It is rec followe
Emergency Contact Person District	As specified	As specified		Mandatory, if used	It is rec followe
Emergency Contact Person State	As specified	As specified		Mandatory, if used	It is rec followe Alterna be use
Emergency Contact Person Pin Code	As specified	As specified		Optional, if used	It is rec followe
Emergency Contact Person Country Code	As specified	As specified	As per ISO Country Codes	Optional, if used	ISO 31 alpha-

Emergency Contact Person Phone Type	Alphanumeric	20	Landline/Mobile/PP-Landline/ Neighbour Landline/Relation Landline /Neighbour Mobile/Relation Mobile	Optional	
Emergency Contact Person Phone Number	Alphanumeric	16	(099)9999999999	Optional	
Emergency Person Email ID	Alphanumeric	255	Must contain '@' and "." at appropriate positions	Optional	
Care Provider Name	As specified	As specified		Optional	It is rec followe
Care Provider Type	Alphanumeric	18	Primary Physician/Consultant/Specialist/Dental Surgeon/Orthodontist/Nurse/Physiotherapist/	Optional	
Care Provider Address Type	Alphanumeric	9	Current/Permanent /Previous	Mandatory, if used, else Optional	
Care Provider Address Line 1	As specified	As specified		Mandatory, if used, else Optional	It is rec followe
Care Provider Address Line 2	As specified	As specified		Optional	It is rec followe

Care Provider City/Town/Village/ Police Station	As specified	As specified		Mandatory, if used, else Optional	It is rec followe
Care Provider District	As specified	As specified		Mandatory, if used	It is rec followe
Care Provider State	As specified	As specified		Mandatory, if used	It is rec followe Alterna be use
Care Provider Pin Code	As specified	As specified		Optional, if used	It is rec followe
Care Provider Country Code	As specified	As specified	As per ISO Country Codes	Optional, if used	ISO 31 alpha-
Care Provider Phone Type	Alphanumeric	20	Landline/Mobile/PP-Landline/ Neighbour Landline/Relation Landline /Neighbour Mobile/Relation Mobile	Optional	
Care Provider Phone Number	Alphanumeric	16	(099)9999999999	Optional	
Care Provider Email ID	Alphanumeric	255	Must contain '@' and "." at appropriate positions	Optional	
Insurance Status	Alphanumeric	9	Insured/Uninsured	Optional	

Insurance ID	Alphanumeric	25	As appropriate	Mandatory if Insurance Type is Entered, else Optional	
Organ Donor Status	Alphanumeric	1	Y - Yes or N - No	Optional	
Episode Type	Alphanumeric	8	New/Ongoing, alternatively New/Active/Inactive	Optional	
Episode Number	Numeric	6	999999 format – no prefixed 0	Mandatory if Episode Type is Entered, else Optional	For def refer t above; site or
Encounter Type	Alphanumeric	14	Outpatient/Inpatient/Emergency/Investigations	Mandatory	For def refer t above
Encounter Number	Numeric	6	999999 format – no prefixed 0	Mandatory	It must encour assign ensure from d encour approp will ne this is issue, of MD

Encounter Date & Time	Datetime	Fixed	Complete date plus hours, minutes and seconds/Complete date plus hours, minutes, seconds and a decimal fraction of a second	Mandatory; should be auto-inserted by the system from system time that is synchronised with Indian Standard Time	As per
Reason for Visit	Alphanumeric	4096[3]		Mandatory	More t be ent
Present History	Alphanumeric	4096		Optional	
Past History	Alphanumeric	4096		Optional	
Personal History	Alphanumeric	4096		Optional	
Family History	Alphanumeric	4096		Optional	

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[3] Both structured and unstructured data can be used wherever the data type is alphanumeric and data length is 4096 and if ne
This is true for all fields in the Minimum Data Set wherever the field size of 4096 occurs.

Menstrual & Obstetric History	Alphanumeric	4096	LMP, Cycle Duration, Gravida, Parity to be captured as structured data where LMP: date type; Cycle Duration, Gravida, Parity: numeric type;	Optional	Menst availab female
Socio-economic Status	As specified	As specified		Optional	It is rec followe
Immunization History	Alphanumeric	4096		Optional	It is pre captur is pract be poss each va admini (admin
Allergy Status	Alphanumeric	8	Active/Inactive	Optional	
Allergy History	Alphanumeric	4096		Optional/Mandatory if Allergy Status is entered	Allergie generic allow a
Allergy Severity	Alphanumeric	8	Mild/Moderate/Severe	Optional/Mandatory if Allergy Status is entered	

Clinical Exam Vitals Systolic BP	Numeric	3	999 – no preceding 0	Optional	Unit of
Clinical Exam Vitals Diastolic BP	Numeric	3	999 – no preceding 0	Optional	Unit of
Clinical Exam Pulse Rate	Numeric	3	999 – no preceding 0	Optional	Unit of
Clinical Exam Temperature (°C)	Floating	2 digits, 2 decimals	99.99	Optional	Unit of Centigr to be u conver data m system
Clinical Exam Temperature Source	Alphanumeric	6	Oral/Armpit/Groin/ Rectal	Mandatory, if Temperature is captured	
Clinical Exam Respiration Rate	Numeric	3	999 – no preceding 0	Optional	Unit of
Clinical Exam Height (cms)	Floating	3 digits, 2 decimals	999.99	Optional	Unit of if any c like fee be con or data the sys
Clinical Exam Weight (kgs)	Floating	3 digits, 2 decimals	999.99	Optional	Unit of any ot pound be con or data the sys

Blood Group	Alphanumeric	3	A+/A-/B+/B-/AB+/AB-/O+/O-	Optional	
Clinical Exam Observation	Alphanumeric	4096		Mandatory	It is rec be use terms/
Investigation Results	Alphanumeric	4096		Mandatory in Inpatients settings, Optional in others	It is rec used f
Clinical Summary	Alphanumeric	4096		Mandatory	It is rec be use terms/
Diagnosis Type	Alphanumeric	11	Provisional/Final/Admission/Interim/Working/Discharge	Mandatory	
Diagnosis Code Name	As specified	As specified	ICD/SNOMED CT/Free	Mandatory	This de diagno CT/ICD SNOM SNOM recom
Diagnosis Code	As specified	As specified	Coding system dependent	Mandatory	Diagno entries
Diagnosis (Description)	Alphanumeric	4096		Mandatory	
Treatment Plan Investigations	Alphanumeric	4096		Mandatory in Inpatients settings, Optional in others	The us value

Treatment Plan Medication	Alphanumeric	4096		Mandatory	It is pre captur is pract of med someth the tab require
Treatment Plan Procedure	Alphanumeric	4096		Mandatory in Inpatients settings, Optional in others	Should advise
Treatment Plan Referral	Alphanumeric	4096		Optional	For use
Other Treatment Plan Type	Alphanumeric	10	Diet/Life-style/ Others	Optional	
Other Treatment Plan Details	Alphanumeric	4096		Mandatory if Other Treatment Type is selected	
Current Clinical Status	Alphanumeric	255	[Free text]	Mandatory	Captur synony conditi prefera "Reliev "Worse instead
Care Provider Digital Signature	As appropriate	As appropriate	As appropriate	Mandatory only for records related to MLC; optional for others[4]	Please section Owner

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[4] Audit trail requirements would ensure that every record is associated with a unique date-time stamp of the entry and the us RBAC (login with unique ID and password) – thereby ensuring that every entry is *de facto* digitally signed.

- All fields from UHID to Organ Donor Status constitutes the demographics information, the rest cli[illegible]al informa represent the header and the latter the body.
- It is strongly recommended that the contents of the header section may only be entered once during registrat as necessary.
- Date of birth, once entered, cannot be changed ever and is thus immutable.
- The contents of the body must be entered anew on every clinical encounter.
- Appropriate search functionality should be provided to ensure that any patient is uniquely identifiable even in identifier (eg, the patient is unable to recall it, has misplaced his/her old records, etc.)

MEDICATION DETAILS (for allopathic system of medicine only):

Data Item	Data Type	Data Length	Format/Values	Status	Additi
Medication Name	As specified	As specified	As per the drug database	Optional; if entered, then some fields are mandatory as specified below	Should
Drug Code	As specified	As specified	As per the drug database	Mandatory, if entered	Auto p
Drug Identifier	As specified	As specified		Optional	GS1 ba
Strength	As specified	As specified	As per the drug database	Mandatory, if entered	Should
Dose	As specified	As specified		Mandatory, if entered	To be e
Route	As specified	As specified		Mandatory, if entered	To be e
Frequency	As specified	As specified		Mandatory, if entered	To be e
Duration	As specified	As specified		Mandatory, if entered	To be e this rep the me

Table 6: EHR MDS

- **N.B.** Due to requirements associated with medical tourism, it is recommended that ISVs keep this in mind whil leaving enough flexibility to enter a foreign district, state and country.

MDS and CEN / TC 251 EN 13606 (EHRCom): The EHRCom standard is recommened for data model specification. T used as reference while designing the Archetypes to ensure archetype level interoperability between different EHF

10. ACRONYMS, DEFINITIONS & GLOSSARY

[A]

ADSL (Asymmetric Digital Subscriber Line): A type of DSL that uses copper telephone lines to transmit data faster than a traditional modem. ADSL only works within short distances because it uses high frequencies with short signals.

Allergy List: This is a list of all the patient's allergies.

Allopathic, Allopathy: Defined as relating to or being a system of medicine that aims to combat disease by using remedies (as drugs or surgery) which produce effects that are different from or incompatible with those of the disease being treated

Ambulatory care: Any medical care delivered on an outpatient basis.

ANM: Auxillary Nurse Midwife

ASHA: Accredited Social Health Activist is usually a literate 25 - 45 yr old married/ widowed/ divorced lady selected from the village itself and accountable to it and trained to work as an interface between the community and the public health system. This is position is one of the key components of the National Rural Health Mission aimed at providing every village in the country with a trained female community health activist

ATC: Anatomical Therapeutic Chemical Classification System,controlled by the WHO Collaborating Centre for Drug Statistics Methodology (WHOCC), is used for drug classification.

Authentication: The verification of the identity of a person or process.

Authorization: Any document designating any permission. Authorization or waiver of authorization for the use or disclosure of identifiable health information for research (among other activities) is required. The authorization must indicate if the health information used or disclosed is existing information and/or new information that will be created. The authorization form may be combined with the informed consent form, so that a patient need sign only one form. An authorization must include the following specific elements: a description of what information will be used and disclosed and for what purposes; a description of any information that will not be disclosed, if applicable; a list of who will disclose the information and to whom it will be disclosed; an expiration date for the disclosure; a statement that the authorization can be revoked; a statement that disclosed information may be re-disclosed and no longer protected; a statement that if the individual does not provide an authorization, she/he may not be able to receive the intended treatment; the subject's signature and date.

AYUSH: Ayurveda, Yoga, Unani, Siddha and Homeopathy. Falls under the broad category of Indian Systems of Medicines and Homoeopathy (ISM&H) governed by Ministry of Health and Family Welfare, Government of India

[C]

- **CCD (Continuity of Care Document):** A joint effort of HL7 International and ASTM. CCD fosters interoperability of clinical data by allowing physicians to send electronic medical information to other providers without loss of meaning and enabling improvement of patient care. CCD is an implementation guide for sharing Continuity of Care Record (CCR) patient summary data using the HL7 Version 3 Clinical Document Architecture (CDA), Release 2. It establishes a rich set of templates representing the typical sections of a summary record, and these same templates for vital signs, family history, plan of care, and so on can then be used for establishing interoperability across a wide range of clinical use cases.

CDT: Common Dental Terminology

Chain of Trust Agreement: A contract needed to extend the responsibility to protect health care data across a series of sub-contractual relationships.

Chief Complaint (**CC**), **Reason for Consultation (RFC), Reason for Visit (ROV):** for recording a patient's disease symptoms.

Client/Serverarchitecture: An information-transmission arrangement, in which a client program sends a request to a server. When the server receives the request, it disconnects from the client and processes the request. When the request is processed, the server reconnects to the client program and the information is transferred to the client. This usually implies that the server is located on site as opposed to the ASP (Application Server Provider) architecture.

Clinical Care Provider: Personnel or entities directly related to providing clinical care to patient.

Clinical Data Repository (**CDR**): A real-time database that consolidates data from a variety of clinical sources to present a unified view of a single patient. It is optimized to allow clinicians to retrieve data for a single patient rather than to identify a population of patients with common characteristics or to facilitate the management of a specific clinical department.

Clinical Decision Support System (**CDSS**): A clinical decision support system (CDSS) is software designed to aid clinicians in decision making by matching individual patient characteristics to computerized knowledge bases for the purpose of generating patient-specific assessments or recommendations.

Clinical Establishment:Clinical establishment means (1) a hospital, maternity home, nursing home, dispensary, clinic, sanatorium or an institution by whatever name called that offers services, facilities requiring diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognised system of medicine established and administered or maintained by any person or body of persons, whether incorporated or not; or (2) a place established as an independent entity or part of an establishment referred to above, in connection with the diagnosis or treatment of diseases where pathological, bacteriological, genetic, radiological, chemical, biological investigations or other diagnostic or investigative services with the aid of laboratory or other medical equipment, are usually carried on, established and administered or maintained by any person or body of persons, whether incorporated or not. (Clinical Establishment Act – CEA 2010)

Clinical Guidelines (**Protocols**): Clinical guidelines are recommendations based on the latest available evidence for the appropriate treatment and care of a patient's condition.

Clinical Messaging: Communication of clinical information within the electronic medical record to other healthcare personnel.

Coded Data: Data are separated from personal identifiers through use of a code. As long as a link exi[illegible] data are considered indirectly identifiable and not anonymous or anonymized.

Code Set: Any set of codes used to encode data elements, such as tables of terms, medical concepts, medical diagnostic codes, or medical procedure codes. This includes both the codes and their descriptions.

Coding: A mechanism for identifying and defining physicians' and hospitals' services. Coding provides universal definition and recognition of diagnoses, procedures and level of care. Coders usually work in medical records departments and coding is a function of billing. Medicare fraud investigators look closely at the medical record documentation, which supports codes and looks for consistency. Lack of consistency of documentation can earmark a record as "up-coded" which is considered fraud. A national certification exists for coding professionals and many compliance programs are raising standards of quality for their coding procedures.

Computer-Based Patient Record (CPR): A term for the process of replacing the traditional paper-based chart through automated electronic means; generally includes the collection of patient-specific information from various supplemental treatment systems, i.e., a day program and a personal care provider; its display in graphical format; and its storage for individual and aggregate purposes. CPR is also called "digital medical record" or "electronic medical record".

Computerized Patient Record (CPR): Also known as an EMR or, when in context, EHR. A patient's past, present, and future clinical data stored in a server.

Computerized Physician Order Entry (CPOE): A system for physicians to electronically order labs, imaging and prescriptions

CPT (Current Procedural Terminology) Code: A recognizable five-digit number used to represent a service provided by a healthcare provider. It is a manual that assigns five digit codes to medical services and procedures to standardize claims processing and data analysis. The coding system for physicians' services developed by the CPT Editorial Panel of the American Medical Association.

[D]

Data Content: All the data elements and code sets inherent to a transaction, and not related to the format of the transaction.

Data: This is factual information (as measurements or statistics) used as a basis for reasoning, discussion, or calculation. It additionally points to the information output by a sensing device or organ that includes both useful and irrelevant or redundant information and must be processed to be meaningful.

Database Management System (DBMS): The separation of data from the computer application that allows entry or editing of data.

DICOM (Digital Imaging and Communications in Medicine): Digital Imaging and Communications in Medicine (DICOM) is a standard to define the connectivity and communication between medical imaging devices.

Disease Management: A type of product or service now being offered by many large pharmaceutical companies to get them into broader healthcare services. Bundles use of prescription drugs with physician and allied professionals, linked to large databases created by the pharmaceutical companies, to treat people with specific diseases. The claim is that this type of service provides higher quality of care at more reasonable price than alternative, presumably more fragmented, care. The development of such products by hugely capitalized companies should be the entire indicator necessary to convince a provider of how the healthcare market is changing. Competition is coming from every direction—other providers of all types, payers, employers who are developing their own in-house service systems, the drug companies.

Document Imaging: Is a process of converting paper documents into an electronic format usually through a scanning process.

Document Management: The Document Manager allows the medical institution to store vital patient documents such as X-Ray's, Paper Reports, and Lab Reports etc.

Documentation: The process of recording information.

DOHAD:Developmental Origins of Health and Diseases

Drug Formulary: Varying lists of prescription drugs approved by a given health plan for distribution to a covered person through specific pharmacies. Health plans often restrict or limit the type and number of medicines allowed for reimbursement by limiting the drug formulary list. The list of prescription drugs for which a particular employer or State Medicaid program will pay. Formularies are either "closed," including only certain drugs or "open," including all drugs. Both types of formularies typically impose a cost scale requiring consumers to pay more for certain brands or types of drugs. See also Formulary.

Drug Formulary Database: This EMR feature is used for electronic prescribing, electronic medical record (EMR), and computerized physician order entry (CPOE) systems to present formulary status to the provider while during the prescribing decision.

DSM: Diagnostic and Statistical Manual for Mental Diseases

[E]

EDI: Acronym for Electronic Data Interchange. Electronic communication between two parties, generally for the filing of electronic claims to payers.

EDI Translator: Used in electronic claims and medical record transmissions, this is a software tool for accepting an EDI transmission and converting the data into another format, or for converting a non-EDI data file into an EDI format for transmission. See also Electronic Data Interchange.

EHR/EMR System Designer, Developer, Manufacturer, Vendor, Supplier, Retailer, Re-seller: Any entity that is involved in the design, development, testing, manufacturing, supplying, selling including re-selling of Electronic Health Records or Electronic Medical Records Systems as a whole or part thereof.

Electronic Data Interchange (EDI): The automated exchange of data and documents in a standardized format. In health care, some common uses of this technology include claims submission and payment, eligibility, and referral authorization. This refers to the exchange of routine business transactions fr[illegible] one computer to another in a standard format, using standard communications protocols.

Electronic Health Records (EHR): is a distributed personal health record in digital format. The EHR provides secure, real-time, patient-centric information to aid clinical decision-making by providing access to a patient's health information at the point of care. Patient health records including treatment history, medical test reports, and images stored in an electronic format that can be accessed by healthcare providers on a computer network

Electronic Medical Records (EMR): A computer-based record containing health care information. This technology, when EMR fully developed, meets provider needs for real-time data access and evaluation in medical care. Together with clinical workstations and clinical data repository technologies, it provides the mechanism for longitudinal data storage and access. A motivation for healthcare entities to implement this technology derives from the need for medical outcome studies, more efficient care, speedier communication among providers and management of health plans. This record may contain some, but not necessarily all, of the information that is in an individual's paper-based medical record.

Electronic protected health information (ePHI): Electronic protected health information (ePHI) is any protected health information (PHI) that is created, stored, transmitted, or received electronically. Electronic protected health information includes any medium used to store, transmit, or receive PHI electronically. The following and any future technologies used for accessing, transmitting, or receiving PHI electronically are covered. Media containing data at rest (data storage) like personal computers with internal hard drives used at work, home, or traveling, external portable hard drives, including iPods and similar devices, magnetic tape, removable storage devices, such as USB memory sticks, CDs, DVDs, and floppy disks, PDAs and smartphones and data in transit, via wireless, Ethernet, modem, DSL, or cable network connections, Email, File transfer. (For Protected Health Information – PHI, please see below)

Encounter: A clinical encounter is defined by ASTM as "(1) an instance of direct provider/practitioner to patient interaction, regardless of the setting, between a patient and a practitioner vested with primary responsibility for diagnosing, evaluating or treating the patient's condition, or both, or providing social worker services. (2) A contact between a patient and a practitioner who has primary responsibility for assessing and treating the patient at a given contact, exercising independent judgment." Encounter serves as a focal point linking clinical, administrative and financial information. Encounters occur in many different settings -- ambulatory care, inpatient care, emergency care, home health care, field and virtual (telemedicine). [http://www.ncvhs.hhs.gov/040127p1.htm]

Episode: An episode of care consists of all clinically related services for one patient for a discrete diagnostic condition from the onset of symptoms until the treatment is complete [http://www.ncmedsoc.org/non_members/pai/PAI-FinalWorkbookforVideo.pdf] Thus, for every new problem or set of problems that a person visits his/her clinical care provider, it is considered a new episode. Within that episode the patient will have one to many encounters with his/her clinical care providers till the treatment for that episode is complete. Even before the resolution of an episode, the person may have a new episode that is considered as a distinctly separate event altogether. Thus, there may be none, one or several ongoing active episodes. All resolved episodes are considered inactive. Hence they become part of the patient's past history. A notable point here is that all chronic diseases are considered active and may never get resolved during the life-time of the person, e.g., diabetes mellitus, hypertension, etc.

EPR: Broadly defined, a personal health record is the documentation of any form of patient information–including medical history, medicines, allergies, visit history, or vaccinations–that patients themselves may view, carry, amend, annotate, or maintain. Today, when we refer to PHRs, we typically mean an online personal health record–which may variously be referred to as an ePHR, an Internet PHR, an Internet medical record, or a consumer Internet Medical Record (CIMR). Generally, such records are maintained in a secure and confidential environment, allowing only the individual, or people authorized by the individual, to access the medical information. Not all electronic PHRs are Internet PHRs. PC-based PHRs may be set up to capture medical information offline.

Evidence Based Medicine: Evidence-based medicine (EBM) is the integration of best research evidence with clinical expertise to aid in the diagnosis and management of patients.

[F]

Family History: A list of the patient's family medical history including the chronic medical problems of parents, siblings, grandparents, etc.

FHIR: Fast Health Interoperable Resources, the newest version from HL7 org for messaging.

Formatting and Protocol Standards: Data exchange standards which are needed between CPR systems, as well as CPT and other provider systems, to ensure uniformity in methods for data collection, data storage and data presentation. Proactive providers are current in their knowledge of these standards and work to ensure their information systems conform to the standards.

Formulary: An approved list of prescription drugs; a list of selected pharmaceuticals and their appropriate dosages felt to be the most useful and cost effective for patient care. Organizations often develop a formulary under the aegis of a pharmacy and therapeutics committee. In HMOs, physicians are often required to prescribe from the formulary. See also Drug Formulary.

[G]

Growth Chart: A feature for a Primary Care or EMR that can be used for paediatric patients. Age, height, weight, and head measurements can be entered over the patient's lifetime, and the feature creates a line graph.

[H]

Health Care Operations: Institutional activities that is necessary to maintain and monitor the operations of the institution. Examples include but are not limited to: conducting quality assessment and improvement activities; developing clinical guidelines; case management; reviewing the competence or qualifications of health care professionals; education and training of students, trainees and practitioners; fraud and abuse programs; business planning and management; and customer service. Under the HIPAA Privacy Rule, these are allowable uses and disclosures of identifiable information "without specific authorization." Research is not considered part of health care operations.

Health Care, Healthcare: Care, services, and supplies related to the health of an individual. Health care includes preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, among other services. Healthcare also includes the sale and dispensing of prescription drugs or devices.

Health Information: Information in any form (oral, written or otherwise) that relates to the past, present or future physical or mental health of an individual. That information could be created or received by a health care provider, a health plan, a public health authority, an employer, a life insurer, a school, a university or a health care clearinghouse. All health information is protected by state and federal confidentiality laws and by HIPAA privacy rules.

Health Level Seven (HL7): A data interchange protocol for health care computer applications that simplifies the ability of different vendor-supplied IS systems to interconnect. Although not a software program in itself, HL7 requires that each healthcare software vendor program HL7 interfaces for its products. The organisation is one of the American National Standards Institute accredited Standard Developing Organization (SDO) - Health Level 7 domain is the standards for electronic interchange of clinical, financial and administrative info among healthcare oriented computer systems. Is a not-for-profit volunteer organization. It develops specifications, most widely used is the messaging standard that enables disparate health care applications to exchange key sets of clinical and administrative data. It promotes the use of standards within and among healthcare organizations to increase the effectiveness and efficiency of healthcare delivery. It is an international community of healthcare subject matter experts and information scientists collaborating to create standards for the exchange, management and integration of electronic healthcare information.

Health: The state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity. It is recognized, however, that health has many dimensions (anatomical, physiological, and mental) and is largely culturally defined. The relative importance of various disabilities will differ depending upon the cultural milieu and the role of the affected individual in that culture. Most attempts at measurement have been assessed in terms or morbidity and mortality.

Healthcare provider: A health care provider is an individual or an institution that provides preventive, curative, promotional or rehabilitative health care services in a systematic way to individuals, families or communities. An individual health care provider may be a health care professional, an allied health professional, a community health worker, any or other person trained and knowledgeable in medicine, nursing or other allied health professions, or public/community health workers like , ASHA, ANM, midwives, paramedical staff, OT/lab/radio-diagnostic technicians, etc. An institution will include hospitals, clinics, primary care centres and other service delivery points of health care individual clinics, polyclinics, diagnostic centres, etc., i.e., any place where a medical record is generated during a patient-care provider encounter (in conformance to CEA 2010 – please refer to Clinical Establishment item above). It must be noted that any person solely performing non-clinical work is not a care provider.

History of Present Illness (HPI): The HPI is the history of the patient's chief complaint.

Human Subject: Refers to a living subject participating in research about whom directly or indirectly identifiable health information or data are obtained or created.

Hybrid Record: Term used for when a provider uses a combination of paper and electronic medical records during the transition phase to EMR.

[I]

Independent Software Vendor (ISV): A company specializing in making or selling software products that runs on one or more computer hardware or operating system platforms.

- **Immunisation:** A complete list of all immunizations that the patient has had.

Informatics: The application of computer technology to the management of information.

Integration: Integration allows for secure communication between enterprise applications.

Interface: A means of communication between two computer systems, two software applications or two modules. Real time interface is a key element in healthcare information systems due to the need to access patient care information and financial information instantaneously and comprehensively. Such real time communication is the key to managing health care in a cost effective manner because it provides the necessary decision-making information for clinicians, providers, other stakeholders, etc.

International Classification of Diseases: This is the universal coding method used to document the incidence of disease, injury, mortality and illness. A diagnosis and procedure classification system designed to facilitate collection of uniform and comparable health information. The ICD-9-CM was issued in 1979. This system is used to group patients into DRGs, prepare hospital and physician billings and prepare cost reports. Classification of disease by diagnosis codified into six-digit numbers. See also coding.

International Classification of Traditional Medicine (ICTM): The World Health Organization, in consultation with a large group of stakeholders in the areas of Traditional Medicine or Complementary and Alternative Medicine and Health Information Systems, has developed a collaborative project plan to produce an international standard terminology and classification system for Traditional Medicine. The mission is to produce an international standard for information on TM that is ready for electronic health records and that will serve as a standard for scientific comparability and communication. With International Classification of Traditional Medicine, International Standard Terminologies of Traditional Medicine, and a web portal that links the TM classification and TM terminologies to the WHO-FIC as the listed deliverables.

International Health Terminology Standards Development Organization (IHTSDO): Denmark-based organization that maintains and licenses SNOMED codes worldwide.

Interoperability: The capability to provide successful communication between end-users across a mixed environment of different domains, networks, facilities and equipment.

ISP: Internet Service Provider

ISV (Independent Software Vendor): An independent software vendor (ISV) is a company specializing in making or selling software, designed for mass or niche markets. This typically applies for application-specific or embedded software, from other software producers.

[J]

J-Codes: A subset of the HCPCS Level II code set with a high-order value of “J” that has been used to identify certain drugs and other items.

[L]

LAN (Local Area Network): A LAN supplies networking capability to a group of computers in clo[illegible] proximity to each other such as in an office building, a school, or a home.

Legacy System Integration: The integration of data between a legacy system and some other software program most commonly using HL-7 standards.

Legacy Systems: Computer applications, both hardware and software, which have been inherited through previous acquisition and installation. Most often, these systems run business applications that are not integrated with each other. Newer systems which stress open design and distributed processing capacity are gradually replacing such systems.

Length of Stay (LOS): The duration of an episode of care for a covered person. The number of days an individual stays in a hospital or inpatient facility. May also be reviewed as Average Length of Stay (ALOS).

LEPR (Longitudinal Patient Record): Longitudinal Patient Record is an EHR that includes all healthcare information from all sources.

Logical Observation Identifiers Names and Codes (LOINC®): The purpose of LOINC® is to facilitate the exchange and pooling of clinical results for clinical care, outcomes management, and research by providing a set of universal codes and names to identify laboratory and other clinical observations. The Regenstrief Institute Inc., an internationally renowned healthcare and informatics research organization, maintains the LOINC database and supporting documentation, and the RELMA mapping program.

[M]

Management Information System (MIS): The common term for the computer hardware and software that provides the support of managing the plan.

Master Patient / Member Index: An index or file with a unique identifier for each patient or member that serves as a key to a patient's or member's health record.

Maximum Defined Data Set: All of the required data elements for a particular standard based on a specific implementation specification. An entity creating a transaction is free to include whatever data any receiver might want or need. The recipient is free to ignore any portion of the data that is not needed to conduct their part of the associated business transaction, unless the inessential data is needed for coordination of benefits.

MCI: Medical Council of India

Medical Code Sets: Codes that characterize a medical condition or treatment. These code sets are usually maintained by professional societies and public health organizations. Compare to administrative code sets.

Medical Informatics: Medical informatics is the systematic study, or science, of the identification, collection, storage, communication, retrieval, and analysis of data about medical care services to improve decisions made by physicians and managers of health care organizations. Medical informatics will be as important to physicians and medical managers as the rules of financial accounting are to auditors.

11

- **Medical Management Information System (MMIS):** A data system that allows payers and purchasers to track health care expenditure and utilization patterns. It may also be referred to as Health Information System (HIS), Health Information Management (HIM) or Information System (IS). See also Electronic Medical Record (EMR).

MIMS: Monthly Index of Medical Specialities

Minimum Data Set: The minimum set of data elements that must be captured, stored, made available for retrieval, presentation, relay and sharing by an EHR system. It comprises of all of the essential data elements required for implementation. An entity creating a transaction must include the mandatory data elements at all times and is free to exclude optional data elements. The entity is free to additionally include whatever other data elements that any receiver might want or need. The recipient is free to ignore any portion of the data that is not mandatory and is further free to ignore any other portion of the data that is not needed to conduct their part of the associated transaction, unless required by sender, intermediaries or receiver. This minimum data set represents the most common data, and system designers are at liberty to add to it as they deem necessary to enrich or enhance their EHR systems.

Modifier: Additional character of a code added to an existing code that is used to help in extending or localization of the existing code.

[N]

NANDA: North American Nursing Diagnosis Association

National Council for Prescription Drug Programs: An ANSI-accredited group that maintains a number of standard formats for use by the retail pharmacy industry.

Non-Participating Physician (or Provider): A provider, doctor or hospital that does not sign a contract to participate in a health plan, usually which requires reduced rates from the provider. In the Medicare Program, this refers to providers who are therefore not obligated to accept assignment on all Medicare claims. In commercial plans, non-participating providers are also called out of network providers or out of plan providers. If a beneficiary receives service from an out of network provider, the health plan (other than Medicare) will pay for the service at a reduced rate or will not pay at all.

[O]

Open Access: A term describing a member's ability to self-refer for specialty care. Open access arrangements allow a member to see a participating provider without a referral from another doctor. Health plan members' abilities, rights or invitation to self refer for specialty care. Also called Open Panel.

openEHR:openEHR is an open standard specification in health informatics that describes the management and storage, retrieval and exchange of health data in electronic health records (EHRs). In openEHR, all health data for a person is stored in a "one lifetime", vendor-independent, person-centred EHR. Maintained by the openEHR Foundation, these are based on a combination of 15 years of European and Australian research and development into EHRs and new paradigms, including what has become known as the archetype methodology for specification of content and include information and service models for the EHR, demographics, clinical workflow and archetypes. They are designed to be the basis of a medico-legally sound, distributed, versioned EHR infrastructure.

70

OR: Operating Room – synonymous to OT as below

OT: Operation Theatre

OTC: Over the counter (drugs). Refers to those drugs that are available off the shelf without any prescription or advise from a registered medical practitioner

Outcome: A clinical outcome is the "change in the health of an individual, group of people or population which is attributable to an intervention or series of interventions". (Taken from: Frommer, Michael; Rubin, George; Lyle, David (1992)."The NSW Health Outcomes program". New South Wales Public Health Bulletin 3: 135. doi:10.1071/NB92067)

Outpatient Care: Care given a person who is not bedridden. It is also called ambulatory care. Many surgeries and treatments are now provided on an outpatient basis, while previously they had been considered reason for inpatient hospitalization. Some say this is the fastest growing segment of healthcare

[P]

Participating Physician: A primary care physician in practice in the payer's managed care service area who has entered into a contract.

Past History: A list of a patient's past health problems, surgeries and specialists.

Patient Demographics: All patient's pertinent information such as first and last name, SSN, DOB, insurance, etc.

Patient Portal: A secure web-based system that allows a patient to register for an appointment, schedule an appointment, request prescription refills, send and receive secure patient-physician messages, view lab results, pay their bills electronically, access physician directories.

Patient: A person who is under medical care or treatment

PC Based: A program designed to run on an individual PC. This typically means data is not shared in real time among other PCs (users).

PCP: Primary care physician who often acts as the primary gatekeeper in health plans. That is, often the PCP must approval referrals to specialists. Particularly in HMOs and some PPOs, all members must choose or are assigned a PCP.

PHR: A personal health record or PHR is typically a health record that is initiated and maintained by an individual. An ideal PHR would provide a complete and accurate summary of the health and medical history of an individual by gathering data from many sources and making this information accessible online.

Picture Archive Communication System (PACS): Used by radiology and diagnostic imaging organizations to electronically manage information and images

9

- **Practice Parameters, Practice Guidelines:** Systematically developed statements to standardize care and to assist in practitioner and patient decisions about the appropriate health care for specific circumstances. Practice guidelines are usually developed through a process that combines scientific evidence of effectiveness with expert opinion. Practice guidelines are also referred to as clinical criteria, protocols, algorithms, review criteria, and guidelines. The American Medical Association defines practice parameters as strategies for patient management, developed to assist physicians in clinical decision-making. Practice parameters may also be referred to as practice options, practice guidelines, practice policies, or practice standards.

Prescription Drug: Drug that the law says can only be obtained by prescription.

Primary Care Physician: A "generalist" such as a family practitioner, pediatrician, internist, or obstetrician. In a managed care organization, a primary care physician is accountable for the total health services of enrollees including referrals, procedures and hospitalization. Also see Primary Care Provider.

Primary Care Provider: The provider that serves as the initial interface between the member and the medical care system. The PCP is usually a physician, selected by the member upon enrollment, who is trained in one of the primary care specialties who treats and is responsible for coordinating the treatment of members assigned to his/her plan.

Primary Care: Basic or general health care usually rendered by general practitioners, family practitioners, internists, obstetricians and pediatricians who are often referred to as primary care practitioners or PCPs. Professional and related services administered by an internist, family practitioner, obstetrician-gynecologist or pediatrician in an ambulatory setting, with referral to secondary care specialists, as necessary.

Principal Diagnosis: The medical condition that is ultimately determined to have caused a patient's admission to the hospital. The principal diagnosis is used to assign every patient to a diagnosis related group. This diagnosis may differ from the admitting and major diagnoses.

Privacy Standards: The Privacy standards restrict the use & disclosure of individually identifiable health information. Privacy standard applies to all protected health information may it is in physical or electronic form.

Privacy: Privacy means an individual's interest in limiting who has access to personal health care information. Specific patient authorization is required for use and disclosure of clinical notes. As per Fernando & Dawson, 2009, privacy is control of access to private information avoiding certain kinds of embarrassment and can be shared or not shared with others; Only authorized (by the patient) people can view the recorded data or part thereof

Progress Note: The documentation of a patient visit or encounter including all or part of the SOAP format.

Protected health information (PHI): Any individually identifiable information whether oral or recorded in any form or medium that is created, or received by a health care provider, health plan or health care Healthcare provider and relates to past, present, or future physical or mental health conditions of an individual; the provision of health care to the individual; or past, present, or future payment for health care to an individual.

8

[R]

Real Time: The instantaneous sharing of data among a user group. It is common to a client/server database configuration.

Referral: Some insurance companies require that on specific plans a referral must be obtained for certain procedures or visits to specialists. The referral is acquired by the primary care physician (PCP) by contacting the insurance company by phone or mail. This is a request for the service. The referral consists of an authorization code, a number of visits allowed (if applicable) and an expiration date.

Referring Provider: is the provider that referred the patient to a specialist or for a specific procedure.

Relational Database: A database program that stores data in a manner similar to Excel, with the difference being the data elements are related (linked) to each other.

Remote Access: Data travels through a private, protected passage via the Internet, allowing healthcare providers to access from home or another practice location and allows EMR vendor to perform system maintenance off-site

Rendering/Performing Provider: The provider actually treating the patient.

Roles and Access Levels: The role and access level of the user needs to be determined and set by the system administrator. The role determines the access level. While roles may be such as system administrator, medical doctor, registered nurse, medical student, medical assistant, nurse assistant, ancillary nurse, health worker, anganwadi worker, etc., the access levels may include viewing only, viewing/adding/editing only, viewing/adding/editing/deleting, all allowed etc. These need to be set out clearly in the SOP of the facility.

ROS (Review of Systems): A series of questions related to the system(s) that the patient is having complaints about (i.e. respiratory for cold symptoms).

RXNORM: RxNorm is the name of a US-specific terminology in medicine that contains all medications available on US market; it provides normalized names for clinical drugs and links its names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software.

[S]

Secondary Care: Services provided by medical specialists who generally do not have first contact with patients (e.g., cardiologist, urologists, dermatologists). In the U.S., however, there has been a trend toward self-referral by patients for these services, rather than referral by primary care providers. This is quite different from the practice in England, for example, where all patients must first seek care from primary care providers and are then referred to secondary and/or tertiary providers, as needed.

Security Standards: The Security Standards require measures to protect the confidentiality, integrity and availability of e-PHI while it's being stored & exchanged. The security standard applies to all electronic PHI.

⑦

Security: This refers to the methods and techniques adopted to protect privacy and are a defense mechanism from any attack (Hong et al., 2004)

SNOMED: Systemized Nomenclature of Medicine Clinical Terms is the universal health care terminology. It is comprehensive and covers procedures, diseases, and clinical data. SNOMED CT helps to structure and computerize the medical record. It allows for a consistent way of indexing, storing, retrieving and aggregating clinical data across sites of care (i.e. hospitals, doctors offices) and specialties. By standardizing the terminology, the variability in the way data is captured, encoded and used for clinical care of patients and research is reduced. Allows for more accurate reporting of data. It is currently available in English, Spanish and German.

Social History: A description of a patient's social habits and history including marital status, alcohol and drug use and exercise habits.

Solo Practice, Solo Practitioner: A physician who practices alone or with others but does not pool income or expenses. This form of practice is becoming increasingly less common as physicians band together for contracting, overhead costs and risk sharing.

SOP: Standard operating procedures or protocols

SQL: Structured Query Language – is a computer language aimed to store, manipulate and retrieve data stored in relational databases.

Subjective: Section in a progress note where a patient's account of their current problem is documented. Consists of chief complaint, HPI and ROS.

Sx: Abbreviation for symptoms

[T]

T1, T3 line: A high-speed internet connection provided via telephone lines often used by businesses needing internet connection speeds greater than DSL/Cable.

Therapeutic Alternatives: Strong Drug products that provide the same pharmacological or chemical effect in equivalent doses. Also see Drug Formulary.

TPA: Third Party Administrator

Treatment Episode: The period of treatment between admission and discharge from a modality, e.g., inpatient, residential, partial hospitalization, and outpatient, or the period of time between the first procedure and last procedure on an outpatient basis for a given diagnosis. Many healthcare statistics and profiles use this unit as a base for comparisons.

Treatment: The provision of health care by one or more health care providers. Treatment includes any consultation, referral or other exchanges of information to manage a patient's care.

[V]

Vital Statistics: Statistics relating to births (natality), deaths (mortality), marriages, health, and disea[illegible] (morbidity). Vital statistics for the United States are published by the National Center for Health Statistics. Vital statistics can be obtained from CDC, state health departments, county health departments and other agencies. An individual patient's vital statistics in a health care setting may also refer simply to blood pressure, temperature, height and weight, etc.

VPN: Virtual Private Network – A VPN "tunnel" is a secure connection, typically firewall to firewall that provides for remote access to your data server.

[X]

XML (Extensible Markup Language): Used for defining data elements on a Web page and communication between two business systems. Example: Standard messaging system for and EMR to integrate with another software such as a practice management or drug formulary database.

(5)

Minutes of the meeting held on 28th February 2014 to discuss implementation of Electronic Health Record (EHR) in India.

A meeting was held under the chairpersonship of Shri R. K. Jain, Additional Secretary & DG (CGHS), MoHFW on 28th February 2014 at 4:00 P.M. in Room No. 155 A, Nirman Bhawan to discuss the rollout of EHR Standards and establishing an appropriate mechanism for certification & compliance of EHR Standards in India. The list of participants is placed at **Annexure - A**.

2. Additional Secretary & DG (CGHS) welcomed the participants and informed them about the efforts of MoHFW in rolling out of the notified standards. AS & DG (CGHS) also informed the participants that he had discussed, over e-mail , the matter of standardization and interoperability with Mr. Najeeb Al Shorbaji, Director (Knowledge Ethics & Research), WHO (Geneva). Mr. Shorbaji had inter alia, stated that "***IHTSDO had confirmed that they do not anticipate any compatibility issues of SNOMED-CT with the future editions of ICD. Also you may know, it is widely recognised that there is no equivalent to SNOMED-CT that is as comprehensive to describe clinical terminology***"

3. The following decisions were taken after detailed discussions:

a) The license shall be procured by Central Bureau of Health Investigation (CBHI) on behalf of Ministry of Health and Family Welfare (MoHFW) and made available free of cost to the agencies developing software applications so that implementation of EHR Standards may be facilitated.

* b) Considering EHR standards are living documents, they should be reviewed from time to time to ensure compliance with prevailing global standards, devices and equipments.

c) A technological team would be established that should advice organizations on technological options and steps to adhere to EHR standards. Project Director, CBHI have been designated as the focal point for facilitating implementation of EHR Standards.

d) An agency with requisite expertise should be designated to certify the existing and new Electronic Health Record (EHR) products / applications and implementations to ensure compliance to the EHR Standards in India. In this regard, it was decided to approach STQC to enquire with them if they have the requisite expertise and keenness to certify products/applications regarding their compliance to EHR standards. If STQC refuses to take up the task, then CDAC, Pune may be designated as the certifying agency.

(4)

e) A central authority may be setup as a repository of all health Information and to develop a framework for managing privacy and confidentiality related matters of EHR data.

f) A committee of stakeholders under the chairmanship of AS& DG (CGHS) has been constituted to discuss the issues emerging during implementation of EHR.

g) JS (Policy) suggested that a software application for health facilities may be developed and given to various public and private health facilities free of cost to ensure implementation of EHR standards. CDAC volunteered to develop the Hospital Information Management System (HIMS) application compliant to EHR standards. Representatives from Tamil Nadu and Punjab requested that their States may be selected for Piloting the said application.

h) A letter will be send to the States/UTs informing them regarding the EHR Standards of India and requesting them to ensure inclusion of clause on compliance to EHR standards as a prerequisite in RFP/RFQs for all Health related ICT initiatives.

i) Next meeting to discuss the EHR implementation should be scheduled after 3 months with additional representation from agencies engaged in development of software applications.

4. Meeting ended with vote of thanks to the Chair and participants.

Annexure - A

List of Participants

S.No.	Name	Designation	Department / Company	e-mail Ids	Contact Number
1.	N.B.Dhal	Joint Secretary	MoHFW	jsnbdhal@gmail.com	011-23061706
2.	M.Jhalani	Joint Secretary	MoHFW	manoj.jhalani@nic.in-	011-23063687
3.	B.S.Bedi	Advisor	CDAC, Delhi	bedi11@yahoo.com bsbedi11@gmail.com	9868243335
4.	S.B.Bhattacharya	Head – Health Informatics	TCS	sbbhattacharya@gmail.com	9810595261
5.	Rajiv Arora	Chief Operating Officer	NeGD, DeitY	rajiv.arora@negp.gov.in	9868270639
6.	Ashis Panda	Senior Consultant	NeGD, DeitY	ashis.panda@negp.gov.in	9910692941
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14.	Dr. Meenakshi Mahajan	Technical Director	NIC	meenakshi.mahajan@nic.in	9810523085
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17.	Vishal Mane	Senior Research Scientist	Media Lab Asia	vishal99.mane@gmail.com	9312995694
18.	Dr. V.K. Sharma	Founder	Track My Beat India Private Limited	drvishwakirti.sharma@trackmybeat.com	9650001544
19.	Dr. S.K. Thirunavukkarasu	HMIS Deputy Director	Tamil Nadu Health Systems Project	dr.skthiru@gmail.com	9445030800
20.	Dr. P. Sunil Gavaskar	Medical Officer	Tamil Nadu Health Systems	drsunilsarathy@tnhsp.net	9445030725

②

S.No.	Name	Designation	Department / Company	e-mail Ids	Contact Number
			Project		
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22.	Dr. S.B. Gogia	Ex-President	Indian Association for Medical Informatics	gogia7@gmail.com	9810126883
23.	Sidharth Sonawat	Senior Assistant Director	FICCI	sidharth.sonawat@ficci.com	9818304535
24.	S.Swaminathan	General Manager	GSI India	swami@gsiindia.org	9810441987
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26.	N.M.Behera	Deputy Director	IRDA	nmbehera@gmail.com	9490484843
27.	Dr. Kasthile	Addl. Secretary	Govt. of Punjab	drkarthile2007@gmail.com	9888334708
28.	A.P. Singh	DDG	UIDAI	ap.singh@nic.in	9868280493
29.	Dr. N.S. Dharmshaktu	DDG	MoHFW	nsdharmshakti@yahoo.com	750337621
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31.	Prof. S.N. Sarbadhikari	Project Director	CHI, NIHFW	supten@gmail.comsupten@gmail.com s.n.sarbadhikari@nic.in	9717669574
32.	Mr.Antonia Duran	Consultant	WHO , New Delhi		
33.	Dr.Rajesh Narwal	Technical Officer	WHO , New Delhi	narwalr@who.int	98719968672
34.	Dr. Amit Mishra	Consultant	NHSRC	dr.amitmishra@gmail.com	9910011505
35.	Dr. K. Madan Gopal	Senior Technical Expert	RSBY. Ministry of Labor and Employment	kmadangopal@gmail.com	9717773732

①

11. FORMAT FOR MEDICAL RECORDS

(As specified by Medical Council of India under regulation 3.1)

Name of the patient:

Age:

Sex:

Address:

Occupation:

Date of 1st visit:

Clinical note (summary) of the case:

Provisional Diagnosis:

Investigations advised with reports:

Diagnosis after investigation:

Advice:

Follow up

Observations:

Date:

Signature in full

....

Name of Treating Physician

NATIONAL RURAL HEALTH MISSION
राष्ट्रीय ग्रामीण स्वास्थ्य मिशन

सत्यमेव जयते

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
डी-307,निर्माण भवन, नई दिल्ली-110011
Government of India
Ministry of Health & Family Welfare
307-D, Nirman Bhavan, New Delhi - 110011

JITENDRA ARORA
Director
Tel : 011-23062317
E-mail : dir.ehealth@gmail.com

No. : Q-11011/3/2015-eGov
Date: 17th February, 2017

Subject: **Adoption of EHR Standards 2016 & Setting up of "National Resource Centre for EHR Standards (NRCeS)".**

Sir/Madam,

Use of ICT in health care (i.e. eHealth) is progressively becoming an integral part of healthcare systems as eHealth has potential to play a transformational role in health care system, especially under the given challenge of ensuring delivery of affordable, cost effective and quality health care to India's billion-plus population. For achieving optimal benefit from eHealth initiatives, focus on an overall framework to set-up an Interoperable Healthcare ICT environment is imperative.

2. With an objective to promote standardization and to build interoperability amongst various Health IT Systems in the country, so that a uniform standard-based system for creation and maintenance of Electronic Health Records (EHRs) for citizens could be set-up, Ministry of Health & Family Welfare (MoHFW) is undertaking various steps and notified EHR Standards for India in September, 2013.

Being a living document, with the passage of time the EHR Standards 2013 have been duly revised in line with the contemporary developments in the standards ecosystem in the country as well as globally. The revised EHR Standards have been notified in December 2016 and is available at http://www.mohfw.nic.in/showfile.php?lid=4138.

3. I would like to inform you that in order to facilitate adoption of the entire set of notified EHR Standards in the country, Ministry has engaged **Centre for Development of Advanced Computing (C-DAC), Pune** to set-up and manage **"National Resource Centre for EHR Standards (NRCeS)"** for providing assistance in developing, implementing and using EHR standards effectively in healthcare applications in India. NRCeS would also support the proposed National eHealth Authority (NeHA) in due course of time to facilitate adoption of EHR standards for development of an **"inter-operable Health IT ecosystem"** in the country which would lead towards creation of standard compliant EHRs of citizens. NRCeS will also support in drafting and firming up national roadmap & strategy for adoption of eHealth/mHealth/Telemedicine applications in the country.

4. The current role of interim National Release Centre (iNRC, www.snomdectnrc.in) for SNOMED CT, which is the primary terminology for all clinical data, will now come under the purview of the newly set-up NRCeS and the current roles/activities performed by CDAC, Pune in capacity of iNRC for SNOMED CT in India will be subsumed by NRCeS with effect from 1st February, 2017.

5. It is informed that India continues to be a member-country of IHTSDO and as decided by the Ministry SNOMED CT remains to be available free of cost to vendors/ developers/ clinical entities for use in India through NRCeS, CDAC- Pune.

6. With a robust standards compliant EHR system and other health IT systems in place, States/UTs will be able to improve medical record keeping, promote the practice of evidence-based medicine, accelerate research, build effective medical practices, ensure safety etc. to improve the overall quality of health care delivery. All the States/UTs are requested to adhere to the notified EHR Standards 2016 for India. In this regard, you are suggested to ensure inclusion of all the relevant clauses required for compliance to the notified **EHR Standards 2016** as a prerequisite in RFP/RFQs for all health IT initiatives.

7. In case of any clarification in this regard, Shri Jitendra Arora, Director (eHealth), MoHFW (jitendra.arora@gov.in); Shri Gaur Sunder, Principal Technical Officer, CDAC Pune (nrc-help@cdac.in); or Shri Chandrasen Shrivastava, Project Lead (eHealth), MoHFW (Chandra_works2001@yahoo.com) may be contacted.

With kind regards,

Yours sincerely,

(Jitendra Arora)

1. The Principal Secretary (Health) / Secretary (Health) of all States/UTs.
2. The Mission Director (MD) of NHM of all States/UTs
3. The Director/Medical Superintendent of Central Government and Autonomous Hospitals.

Copy to:

1. Shri. Gaur Sunder, Principal Technical Officer, C-DAC, Pune
2. Project Director, CHI, NIHFW, Delhi

Charu Khatter <khattercharu32@gmail.com>

Fwd: Adoption of EHR Standards 2016 & Setting up of “National Resource Centre for EHR Standards (NRCeS)”.

1 message

Amit Kumar <amitkumariss34@gmail.com> Fri, Feb 17, 2017 at 4:59 PM
To: Charu Khatter <khattercharu32@gmail.com>, Ashish Sharma <ashish.sharma.css@gmail.com>

---------- Forwarded message ----------

From: **JITENDRA ARORA DIRECTOR** <jitendra.arora@gov.in>
Date: Fri, Feb 17, 2017 at 12:34 PM
Subject: Adoption of EHR Standards 2016 & Setting up of “National Resource Centre for EHR Standards (NRCeS)”.
To: prl.secy.hmfwap@gmail.com, poonam.malakondaiah@gmail.com, udevelop.and@nic.in, hage_kojeen@rediffmail.com, samirksinha69@gmail.com, health-bih@nic.in, secretaryhealthcg@gmail.com, collector-daman-dd@nic.in, collectordaman@gmail.com, pshealth@nic.in, secywcd14@gmail.com, secphfwd@gujarat.gov.in, acshealth2015@gmail.com, healthsecy-hp@nic.in, secyhealthjk@gmail.com, sec-health-jhr@nic.in, hlthdept.fdi@gmail.com, prs-hfw@karnataka.gov.in, secy.hlth@kerala.gov.in, lk-admin@nic.in, lk-coll@nic.in, pshealth@mp.gov.in, psec.pubhealth@maharashtra.gov.in, 1pksingh1@gmail.com, ytsering@yahoo.com, homecomissionernagaland@gmail.com, orhealth@nic.in, secywel.pon@nic.in, pshfwpunjab@gmail.com, phsrajasthan@gmail.com, healthsecyskm@yahoo.com, hfwsec@gmail.com, tshealthpeshi@gmail.com, secy.hfw-tr@gov.in, psecup.health@gmail.com, 2712066@gmail.com, prin.secy.wbhealth@gmail.com, MD Andhra Pradesh <mdnrhmap@gmail.com>, Arunachal Pradesh Mission Director <md-ar-nrhm@nic.in>, Assam Mission Director <mdnrhmasm@gmail.com>, Chhattisgarh Mission Director <mdnrhmcg@yahoo.co.in>, Delhi Mission Director/Secretary <md-del-nrhm@nic.in>, Gujrat Mission Director <md-nrhm@gujarat.gov.in>, Haryana Mission Diector <md-hr-nrhm@nic.in>, Himachal MD <md-hp-nrhm@nic.in>, J&K MD <mdnhmjk@gmail.com>, Karnataka MD <mdnrhmkar@gmail.com>, Maharashtra MD <mdnrhm.mumbai@gmail.com>, Puducherry MD <md-pdy-nrhm@nic.in>, Punjab MD NRHM <mdnrhmpunjab@gmail.com>, Rajasthan MD <md-nrhm-rj@nic.in>, Sikkim MD <mdnrhmsikkim@gmail.com>, Telangana MD NHM <mdnhmts@gmail.com>, UP MD NRHM <mdupnrhm@gmail.com>, Uttarakhand MD <mdnhmuk@gmail.com>, West Bengal MD NRHM <mdnrhm@wbhealth.gov.in>, MD Bihar <ed_shsb@yahoo.co.in>, MD Chandigarh <dhs_ut@yahoo.co.in>, MD CHD <nrhmchd@gmail.com>, MD D&NH <cmodnh@gmail.com>, MD D& N <nrhmdnh@gmail.com>, MD D&D <vindy2002@yahoo.com>, MD GOA <directorhealth_goa@yahoo.co.in>, MD Kerala <arogyakeralam@gmail.com>, MD Lakshadweep <rchlakshadweep@gmail.com>, MD MP <missiondirectormp@gmail.com>, MD MAnipur <okramibomcha@yahoo.co.in>, MD Manipur <shms99@gmail.com>, MD Meghalaya <mebans@yahoo.com>, MD Mizoram <nrhmmizoram@yahoo.com>, MD Nagaland <nrhmnagaland@gmail.com>, MD Odisha <nrhmorissa@ori.nic.in>, MD ODISHA <missiondirector@nic.in>, MD Pondicherry <nrhmpondicherry@yahoo.co.in>, MD TN <rchpcni@tn.nic.in>, MD Telangana <chfw.ts@gmail.com>, MD Telangana <peshichfwts@gmail.com>, MD Tripura <shfws_tripura@yahoo.co.in>, MD UP <ed@sifpsa.org>, Med.sup.rmlh@gmail.com, dpgichd@hotmail.com, dpgi@pgimer.edu.in, pgimer-chd@nic.in, sa-nitrd@nic.in, r.sarin@nitrd.nic.in, dr.ahangar@yahoo.co.in, davidumdor@gmail.com, info.neigrihms@nic.in, dirstaff@nimhans.ac.in, directorlhmc@gmail.com, director-lhmc@gov.in, msoffice@vmmc-sjh.nic.in, msofficesjh@gmail.com, director@rims.edu.in, director@jipmer.edu.in, subhashparija@yahoo.co.in, dean@mgims.ac.in, gargbs@gmail.com, secretary@mgims.ac.in, ashwini@mgims.ac.in, sngaur@gmail.com, admin@vpci.org.in, dram_cip@rediffmail.com, director@aiishmysore.in, Director.aiims@gmail.com, director@aiimsbhopal.edu.in, dean@aiimsbhubaneswar.edu.in, director@aiimsbhubaneswar.edu.in, director@aiimsjodhpur.edu.in, director@aiimspatna.org, admin@aiimspatna.org, director@aiimsraipur.edu.in, admin@aiimsraipur.edu.in, director@aiimsrishikesh.edu.in, rakeshkumar.aoaiims@gmail.com, skdeuri1959@gmail.com, lgbrimh@yahoo.co.in, aiihph@cal.vsnl.net.in, dc.joshi56@nic.in, deepakchaudhary@hotmail.com, drkksinghal@gmail.com
Cc: chandrasen shrivastava <chandra_works2001@yahoo.com>, Sumit Soam <sumitsoam13@gmail.com>, Gurcharan Rajal <mr.rajal@gmail.com>, US SK Pani <skpani2001@yahoo.com>, Amit Kumar <amitkumariss34@gmail.com>, Indu <indubharwal89@yahoo.in>, Ashish Sharma <ashish.sharma91@gov.in>, ANKIT TRIPATHI <ankit_tripathi11@hotmail.com>, "Prof. Sarbadhikari" <supten@gmail.com>, Gaur Sunder <gaurs@cdac.in>, Sunil JS <sunil.sharma62@gov.in>, Manoj Jhalani <manoj.jhalani@nic.in>

Sir/Madam,

MoHFW has envisaged establishing a system for interoperable Electronic Health Records (EHRs) of citizens to be made available and accessible online to facilitate continuity of care, better affordability and better health outcome, better decision support system. With an objective to promote standardization and to build interoperability amongst various Health IT Systems in the country, so thata uniform standard-based system for creation and maintenance of Electronic Health Records (EHRs) for citizens could be set-up, Ministry of Health & Family Welfare (MoHFW) is undertaking various steps and notified EHR Standards for India in September, 2013.

Being a living document, with the passage of time the EHR Standards 2013 have been duly revised in line with the contemporary developments in the standards ecosystem in the country as well as globally. The revised EHR Standards have been notified in December 2016 and is available athttp://www.mohfw.nic.in/showfile.php?lid=4138.

Also in order to facilitate adoption ofthe entire set of notifiedEHR Standards in the country,Ministry has engaged**Centre for Development of Advanced Computing (C-DAC), Pune**to set-up and manage**"National Resource Centre for EHR Standards (NRCeS)"**for providing assistance in developing, implementing and using EHR standards effectively in healthcare applications in India.

In this regard, please find attached the signed copy of DO letter.

--

Regards

Jitendra Arora
Director(eHealth)
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Nirman Bhawan (Room 307D)
New Delhi - 110108.
+91-11-23062317 (Telefax),
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D.O letter dated 17.02.17 reg adoption of EHR standards 2016 an.pdf
731K

Q-11011/3/2015-eGov

Department of Health and Family Welfare
eGovernance Division

* * *

Subject: Periodic Review of Electronic Health Record Standards for India

Ministry of Health and Family Welfare notified Electronic Health Records (EHR) Standards in September 2013 **(F/A)** to encourage standardization, integration and electronic information exchange amongst the various healthcare providers.

2. Subsequently, India become a member of International Health Terminology Standards Development Organization (IHTSDO), Denmark effective from 1st April, 2014, which owns and administers the rights to SNOMED-CT. All the vendors and Healthcare professionals of India can use SNOMED CT for Health IT application to be used in India without paying any license fee.

3. The EHR Standards document is a living document and should be reviewed / updated periodically at a maximum of 24 months interval, as mentioned in the standards document **(F/A)**.

4. Earlier as per the decisions taken in the meeting held on 28th February, 2014 under the chairmanship of AS&DG (CGHS) to discuss implementation of Electronic Health Record (EHR) in India **(F/B)** it is stated that "Considering EHR standards are living documents, they should be reviewed from time to time to ensure compliance with prevailing global standards, devices and equipment's."

5. In view of the above, it is proposed that review of the notified EHR Standards for India be carried out by August 2015 i.e. 24 months from date of notification.

Submitted for your direction please

9/6/2015
Chandrasen Shrivastava
(PM-eGov PMU)

Director (e-Gov) (on-leave)

JS(e-Gov) pl. suggest a committee of 6 - 8 members to take up review of the Standards. Also plee the composition of the original committee 9/6

Dir(egov) -o.L

AD(eGov)

- 2/n -

Reference note on pre-page.

As suggested, the following composition of EHR Review Committee is suggested.

'A'

1. Dr. Supten Sarbadhikari, Project Director (NHP), NIHFW
2. Dr. S. B. Bhattacharya, Head-Health Informatics, TCS
3. Dr. B.S. Bedi, Advisor, CDAC, Delhi
4. Mr. Sunder Gaur, CDAC, Pune
5. Mr. Sunil Bhushan, NIC, Health
6. Dr. Karanvir Singh, CIO, Apollo Hospitals.
7. Representative, DeitY
8. Shri Jitendra Arora, Director (e-Gov), MoHFW .. Convener

Submitted for approval.

(Jitendra Arora)
Director (eGov)
17.06.2015

JS ~~(e-Gov)~~

Notes from pre-page explain. Review of the EHR Standards notified in Sept 2013 has become necessary. The EHR Committee constituted on 13/9/2010 had 18* members & AS & DG chaired the Committee. Later 4 # sub Committees were constituted. ~~The Legal Sub group~~

*F/E

#F/G &
F/H

It is proposed to constitute a Group to review the EHR Standards under the chairmanship of AS&DG, with the membership as proposed at 'A' above.

The non-official members may be paid per diem, hotel accomodation charges & economy class air fare as mentioned ~~at~~ in the order at F/H (constitution

of Legal (Fourth Sub Group). IFD concurrence was taken for such payment to non-official members. ~~E/F~~ A photocopy of the note-sheet is at F/J.
Submitted.

~~8 PH~~/7n

19/6

Office of Secretary (H&FW)
FTS No. 138167
Date 07/07/2015

~~AS & DG~~

AS & FA.

Secretary

Pl discuss - is revision necessary even though these have not yet been implemented?
19/6

19/6
Dir(legal)

~~JS(NBD)~~

Initiatives are being taken by the Ministry for promotion and adoption of the EHR standards. Various vendors / stakeholders are implementing the EHR standards.

Any document on standards is a living document and Standards undergo periodic updates. The EHR Standards document notified in September 2013, mandates for revision within two years. During revision, some matters like incorporation of new developments like ICD updates; necessity of some of other standards; challenges faced in adoption of standards and measures required to address the same etc. may be discussed and appropriately incorporated.

26/6/15

~~JS(NBD)~~

26/6

~~AS&DG~~

May pl. approve.
JS(NBD) may head this group.
6/7

O.K.

~~Secy(HFW)~~

There was some issues regarding SNOWMED. Have they been sorted out with Deity?
7/7/15

AS & DG

JS(NBD)

7/7

Fl. p/u draft Notification of the Committee.

I've apprised Secretary regarding SNOMED-CT.

8/7

Dir(egov). on tour

AD(eGov)

9/7/15

-5-

Q-11011/3/2015-eGov
FTS: 138167

Ministry of Health and Family Welfare notified Electronic Health Record (EHR) Standards in September 2013 (F/A) to encourage standardization, integration and electronic information exchange amongst the various healthcare providers.

2. The EHR Standards document is living document and should be reviewed / updated periodically at a maximum of 24 months interval, as mentioned in the standards document.

3. In view of the above, EHR review Committee has been constituted with the approval of Secretary (HFW) to review the EHR Standards. The composition of the committee is as follows:

1.	Mr. N B Dhal, JS (eGov), D/o HFW	Chairman
2.	Dr Supten Sarbadhikari, Project Director (NHP), NIHFW	Member
3.	Dr. S B Bhattacharya, Head Health Informatics, TCS	Member
4.	Dr B.S. Bedi, Advisor, CDAC, Delhi	Member
5.	Mr. Gaur Sunder, CDAC, Pune	Member
6.	Mr. Sunil Kumar Bhushan, NIC, Health	Member
7.	Dr. Karanvir Singh, CIO, Apollo Hospitals	Member
8.	Representative, DeitY	Member
9.	Mr. Jitendra Arora, Director (eGov), MoHFW	Convener

fo US(Fin.IV)

4. In the committee, the member at Sr. No. 2, 3, 4 and 7 are non official members and all other are official members. Before a formal order regarding constitution of EHR Review Committee is issued, sitting fee and hotel accommodation charges for non official members and TA/DA for official members may be fixed with the approval of IFD so that the same may be incorporated in the office order of constitution of EHR Review Committee to avoid the issues related to payment to the members of the committee in the future.

5. The fourth Sub Group under EHR/ EMR Standards Committee has already been constituted in the Division (Office Order is placed at F/H). The payment structure for the members of this committee is already approved by IFD. In this committee all Out-Station non official members of the Sub Group are eligible for reimbursement of Air Travel by Economy Class/Shortest direct route and hotel accommodation expenses as per actual subject to a ceiling of Rs. 6500/-. All non official members are eligible for reimbursement @ Rs 1500/- per diem as sitting fee for attending the meeting. TA/DA of the official members of the Sub Group for attending the meetings is being met from the same source from which their salary is drawn.

6. We may seek approval of IFD for the payment structure (as mentioned in para 3) to the members of EHR Review Committee.

Submitted please.

AKum
16/7/15
Amit Kumar
AD(eGov)

US (eGov)

16/7

M/o Health & F W
(I.F.D.)
Dy./F T.S. No. 3816/
Date 27/7/15

Dir(eGov)

JS(eGov) on tour

The above committee has been approved by JS/AS/Secty (HFW). IFD may kindly concur for Para 3, 4 above

JArora
16/7/15

IFD

23/7/15

P.F.C

F.No.Q-11011/03/2015-eGov

Integrated Finance Division

Reference note at page 1-5/ante may kindly be perused.

2. This is regarding a proposal of Programme Division seeking financial concurrence of IFD for reimbursement of Air Travel, Hotel Accommodation Expenses and payment of Sitting Fees in respect of non-Official Members and TA/DA for Official Members to the EHR Review Committee Members for attending in the meeting.

3. In the proposal, the Programme Division has stated that the Secretary, HFW has already approved the EHR Review Committee vide at page 3/ante and now they have requested to financial concurrence of IFD for reimbursement of Air Travel, Hotel Accommodation Expenses and payment of Sitting Fees in respect of non-Official Members and TA/DA for Official Members in the line of IFD's earlier concurrence given in last year vide at F/J, which they have mentioned in their note vide in para 5 at page 5/ante.

4. The proposal has also been approved by the JS(e-Gov) in this Ministry vide at page 15/ante

5. Keeping in view of the above, IFD may concur in the proposal as mentioned at para 2 on above.

Submitted please.

(Bishnu P. Kirtania)
Under Secretary (F-IV)
27.07.2015

CD
8778
C- 29/07/15
29/7/15

DY NO: 590/US(F-IV)
27/7/15

Min. of Health & F.W.
A.S. & FA'S Office
FTS No. 138167
Date 28/7/15

~~Director (IFD)~~

28/7

AS&FA

Dir/IFD

~~US(F-IV)~~

29/7

29/7/15

JS (e-Gov)

31/7

31/7/15

Dir(e-gov) on tour
US(eGov)

AD(eGov)

-7-

Ref. foregoing notes.

The draft Order for constitution of EHR Review Committee is placed below for approval pls.

5/8/2015
US(eGov)

FC please

~~Dir (eGov)~~

~~US(eGov)~~

5/8/15

As desired, FC pls

5/8/15

~~Dir(eGov)~~

~~US(eGov)~~

5/8/15

5/8/15

AD(eGov)

Q-11011/3/2015-eGov

FTS: 138167

Ministry of Health and Family Welfare notified Electronic Health Record (EHR) Standards in September 2013 (F/A) to encourage standardization, integration and electronic information exchange amongst the various healthcare providers.

2. The EHR Standards document being a living document should be reviewed / updated periodically at a maximum of 24 months interval, as mentioned in the standards document.

3. In view of the above, EHR review Committee has been constituted with the approval of Secretary (HFW) to review the EHR Standards. JS (eGov) is the Chairman of the committee. The file is put up for seeking the convenience of JS (eGov) to convene the first meeting of EHR Review committee.

Ashish Sharma 13/8/15
Ashish Sharma
Assistant

AD(eGov)

AKum 13/8/15

US(eGov)

Convenience of JS (eGov) is solicited for convening the 1st meeting of EHR Review Committee pls.

13/8

Dir(eGov)

We may hold in 1st week of September after PRSC of iNRC or we may hold both meetings on same date as the members are almost common.

13/8/15

JS(NBD)

26/8/15

On ~~17/9~~ ~~26/9~~/2015 at 2.30 3.50 pm (iNRL PRC) & 3.30 4:00 pm respectively

14/8

Dir(egov)

14/8/15

AD(eGov)

Ref. to notes on prepage.

A meeting notice is placed below for approval please.

17/8/15

US(eGov) - On leave

~~Dir (eGov)~~

17/8/15

AD (eGov)

Q-11011/3/2015-eGov
FTS: 138167

Ministry of Health and Family Welfare notified Electronic Health Record (EHR) Standards in September 2013 to encourage standardization, integration and electronic information exchange amongst the various healthcare providers.

2. The EHR Standards document is living document and should be reviewed / updated periodically at a maximum of 24 months interval, as mentioned in the standards document.

(F/X)

3. In view of the above, EHR review Committee has been constituted with the approval of Secretary (HFW) to review the EHR Standards. The composition of the committee is as follows:

1.	Mr. N B Dhal, JS (eGov), D/o HFW	Chairman
2.	Dr Supten Sarbadhikari, Project Director (NHP), NIHFW	Member
3.	Dr. S B Bhattacharya, Head Health Informatics, TCS	Member
4.	Dr B.S. Bedi, Advisor, CDAC, Delhi	Member
5.	Mr. Gaur Sunder, CDAC, Pune	Member
6.	Mr. Sunil Kumar Bhushan, NIC, Health	Member
7.	Dr. Karanvir Singh, CIO, Apollo Hospitals	Member
8.	Representative, DeitY	Member
9.	Mr. Jitendra Arora, Director (eGov), MoHFW	Convener

4. The first meeting of EHR Review Committee has been scheduled at 04.00 PM on 26th August 2015. In addition to the aforementioned committee members, the following members may also be called to take part in the proceeding of meeting as 'Special Invitees':

1. Ms. Shobha Mishra Ghosh, Senior Director, FICCI
2. Dr. Rajesh Narwal, Technical Officer, Health System Regulations,WHO
3. Mr. Amit Mishra, Senior Consultant, NHSRC

5. We may also request Sh. K.B. Agarwal, AS, MoHFW to kindly chair the aforementioned meeting.

Submitted please.

JArora
19/8/15
Jitendra Arora
Director (eGov)

~~JS (NBD)~~

Noted above. I had also proposed at P-2/n that AS may chair the committee, please.

20/8

AS (KBA)

JS may chair. I shall join informally. Further, CEO/NISG may also be requested to be present as NISG's association is also planned in many Health Mission components.

20/8

~~JS (NBD)~~

20/8

Dir (egov) on tour

~~AD(eGov)~~

-11-

Ref. notes on prepage.

2. A draft meeting notice for inviting 'special invitees' to attend the meeting is placed below for signature pls.

24/8/15

~~US(eGov)~~

24/8/15

~~Dir(eGov)~~

~~US/eGov~~

24/8

AD(eGov)

FTS: 138167

-12-

Subject: **Minutes of the First Meeting of the Electronic Health Record (EHR) Review Committee held on 26th August, 2015 –reg**

The first meeting of 'EHR Standards Review Committee' was held on 26th August, 2015 in Nirman Bhawan, Ministry of Health & Family Welfare under the Chairmanship of Shri N B Dhal, JS(eGov). The minutes of the same have been prepared and are placed below for your kind perusal / approval please.

Akum
3/9/15

~~US(eGov)~~

3/9/15

~~Dir(eGov)~~

JS may kindly approve MoM dt. 26.8.15

3/9/15

~~JS(NBD)~~

May kindly see before issue.

3/9

~~AS (LK/BA)~~

3/9

~~JS(NBD)~~

~~US(eGov)~~

3/9/15

4/9/15

~~AD(eGov)~~

Akum
4/9/15

~~Asst(AS)~~

A draft office Memorandum for circulating the minutes of meeting is placed below for signature Please.

4/9/15

~~AD(eGov)~~

Akum
4/9/15

~~US(eGov)~~

4/9/15

AD(eGov)

-13-

Q-11011/3/2015-eGov
FTS: 138167

The first meeting of 'EHR Standards Review Committee' was held on 26th August, 2015 in Nirman Bhawan, Ministry of Health & Family Welfare under the Chairmanship of Shri N B Dhal, former JS(eGov), MoHFW. Shri K B Agarwal, AS, MoHFW also joined the meeting. Representatives from WHO, FICCI and NISG attended the meeting as special invitees.

2. In the meeting, it was decided that the Sub-committee comprising Shri B.S. Bedi, Shri Bhattacharya & Shri Gaur Sunder will prepare a draft version of the revised EHR Standards and the same would be presented before the Review Committee in a month's time.

3. The division is in receipt of the draft of the revised 'EHR Standards for India' sent by Shri B S Bedi, CDAC('F/X'). The EHR standards notified by the Ministry in September 2013 are placed at p.6-58/C.

Submitted please.

17/11/15

US (eGov) ref. above.

During the said meeting of the EHR Review Committee, it was decided that the draft version of the revised EHR standards would be placed before the Review Committee (p. 103-107/c). Meeting of the EHR Review Committee may, therefore, be convened for placing the draft before it. JS (eGov) is the Chairman of the Review Committee. Submitted for consideration pls.

17/11/15

Dir (eGov)

All the meetings are to fixed up for 1st & 2nd ~~AD~~ December as discussed with AS (eGov)

17/11/15

US (eGov)

AD (eGov)

18/11/15

Ref. notes on prepage.

The meeting of EHR Review Committee under the Chairmanship of JS(eGov) may be scheduled on 1st December 2015 at 3.00 PM. special Invitees of the last meeting from NISG, FICCI, WHO & NHSRC may also be invited in this meeting. Accordingly ~~two~~ meeting notices ~~are~~ placed below for approval pls.

AKum
19/11/15

US(eGov)

सुनीता डौंडियाल
19/11/15

निदेशक (ई.गव.)

2nd December 11 AM

जितेन्द्र अरोड़ा
19/11/15

US(eGov)

सुनीता डौंडियाल
20/11/2015

सहायक निदेशक (ई.गव.)

As discussed with Dir(eGov), meeting will be held at 11.30 AM on 2/12/15. DFA-I pls.
DFA-II

अजित कुमार
20/11/15

अवर सचिव (ई.गव.)

सुनीता डौंडियाल
20/11/15

सहायक
अवर ~~सहायुक्त~~ ~~संयुक्त~~ निदेशक (ई.गव.)

-15-

Q—11011/3/2015-eGov
FTS: 138167

Subject: Minutes of the Second Meeting of the Electronic Health Record (EHR) Review Committee held on 14th December, 2015

The second meeting of 'EHR Standards Review Committee' was held on 14th December, 2015 at Nirman Bhawan, Ministry of Health & Family Welfare under the Chairmanship of Shri Sunil Sharma, JS (eGovernance). Representatives from WHO attended the meeting as special invitees.

2. The minutes of the same has been prepared by ePMU Team and is placed below for approval.

अमित कुमार
22/12/15
(अमित कुमार)
सहायक निदेशक (ई-गवर्नेंस)

~~अवर सचिव(ई-गवर्नेंस)~~

~~Dir(eGov)~~

सुनीता धौंडियाल
24/12/15

22/12/15

JS(SS)

For kind information.

24/12/15

AS(KBA)

Minutes are ok, but slightly inconclusive in the sense that what facilitation is required in getting list of drugs for incorporation in standards & further the report needs to be finalised by the next meeting.

28/12

JS(SS)

Pl speak.

30/12/15

JS(eGov)

Spoken with JS(eGov)
A Kum
31/12/15

Ref. AS (eGov) remarks on prepage.

2. As discussed with JS (eGov), suggestions were sought from Sh. B.S. Bedi on the remarks of AS (eGov). He has provided his inputs as a form of track change document and revised the draft MoM of second meeting of EHR Review Committee.

✓F/A

3. Based on inputs received from Sh. Bedi, the Revised draft MoM of second meeting of EHR Review Committee has been prepared & is placed below for approval / consideration pls.

अमित कुमार
5/01/16

~~अपर सचिव (ई.गव.)~~

सुनीता डौंडियाल
5/1/16

~~निदेशक (ई०गव०)~~

कृपया जारी करें.
जितेन्द्र अरोड़ा
5/1/16

~~सं० निदेशक (ई गव.)~~

ई-मेल से जारी किया गया।

अमित कुमार
6/1/16

Subject: Meetings of the EHR Review Committee and PRSC of iNRC for SNOMED-CT -reg

The second meeting of 'EHR Standards Review Committee' was held on 14th December, 2015. As per decisions in the meeting, the revised EHR standards document was circulated to all the committee members for their comments. Summary of the comments received from the committee members may be seen at (F/X).

2. The third meeting of Project Review and Steering Committee of iNRC for SNOMED-CT was held on 26th August 2015.

"X" 3. It is proposed to convene the next meeting of EHR Standards Review Committee and PRSC of iNRC for SNOMED-CT to discuss the revised draft of EHR standards and to review the progress of iNRC for promoting use of SNOMED CT in the country

4. Since many of the committee members in both the committees are same, it would be appropriate to convene the meetings on the same day under the chairmanship of JS(eGov).

5. File is submitted for seeking the convenience of JS(eGov) please.

अमित कुमार
9/2/16
(अमित कुमार)
सहायक निदेशक (ई-गवर्नेंस)

निदेशक (ई-गवर्नेंस)

Kindly indicate date & time ~~for~~ during 3rd week of this month to convene two meeting as indicated above "X".

9/2/16

JS(eGov)

24th Feb 11.00 am & 2.00 pm

9/2/16

Dir(eGov)

Lunch may also be arranged

9/2/16

US/eGov)

10/2

AD(eGov)

Draft meeting notices have been prepared & are placed below for approval.

AKumar
11/2/16

Dir (eGov)

11/2/16

AD(eGov)

Q—11011/3/2015-eGov
FTS: 138167

Subject: Minutes of the Second Meeting of the Electronic Health Record (EHR) Review Committee held on 14th December, 2015

The third meeting of 'EHR Standards Review Committee' was held on 24th February, 2015 at Nirman Bhawan, Ministry of Health & Family Welfare under the Chairmanship of Shri Sunil Sharma, JS (eGovernance). Representatives from WHO attended the meeting as special invitees.

2. The draft of the revised "Electronic Health Record (EHR) Standards for India" (Placed at F/A) along with the minutes of the meeting as prepared by ePMU Team (Placed at 'F/B') are placed below for approval please.

आशीष शर्मा 4/3/2016
(आशीष शर्मा)
सहायक अनुभाग अधिकारी(ई गवर्नेंस)

सहायक निदेशक (ई गवर्नेंस)- अवकाश पर

~~**अवर सचिव (ई गवर्नेंस)**~~ सोमा 2/3/16

JS may kindly approve

~~निदे (ई. गव)~~

4/3/16

JS(EG)

सुनील शर्मा 2/3/16

निदेशक (ई गव)

4/3/16

ASO (eGov)

-19-

File no. Q-11011/3/2015-eGov
FTS: 138167

Subject: **Placing of revised EHR standards in public domain.**

The third meeting of 'EHR Standards Review Committee' was held on 24th February 2016 under the chairmanship of Shri Sunil Sharma, JS (eGov), MoHFW. Minutes of meetings are placed at 'F/A'.

2. It was decided in the meeting that the Revised EHR Standards (Placed at F/B) may be placed in public domain for a period of 30 days with the approval of competent authority for comments from general public.

3. A cover ~~letter~~ notice has been prepared and is placed below for placing the EHR Standards in public domain

Submitted please

आशीष शर्मा
(आशीष शर्मा) 15/3/2016
सहायक अनुभाग अधिकारी(ई गवर्नेंस)

~~सहायक निदेशक (ई गवर्नेंस)~~

A metadata form ~~and a notice~~ for placing revised EHR standards on Ministry's website and a notice for seeking comments on Revised EHR standards is placed below for approval please.

F/X ✓

F/Y

अजीत कुमार
15/3/16

~~US(eGov)~~ सोमा 16/3/16

16/3/16

~~निदे (ई गव)~~

~~JS(SJ)~~

17/3/16

~~निदेशक (ई गव)~~

AD(eGov)

17/3/16

File no. Q-11011/3/2015-eGov
FTS: 138167

Subject: **Placing of revised EHR standards in public domain.**

The third meeting of 'EHR Standards Review Committee' was held on 24th February 2016 under the chairmanship of Shri Sunil Sharma, JS (eGov), MoHFW. Minutes of meetings are placed at 'F/A'.

2. It was decided in the meeting that the Revised EHR Standards may be placed in public domain for a period of 30 days with the approval of competent authority for comments from general public. The revised EHR standard has been uploaded on Ministry's website. The last date for seeking comments from various stakeholders on the revised documents is 20th April, 2016.

3. Given the scope of coverage, relationship to so many international standards, it requires detailed study and informed comments by a wide cross-section of stakeholders. It is proposed to extend the last date for seeking comment upto 20th May, 2016.

4. Also Hindi version of revised EHR standards (placed at F/B) form is to be uploaded at Ministry's website.

5. In this regards, a cover letter for extending the last date of seeking comments on revised EHR standards and a Meta Data form for uploading the Hindi version of revised EHR standards are placed below for approval/signature please.

आशीष शर्मा
18/4/2016
(आशीष शर्मा)
सहायक अनुभाग अधिकारी(ई गवर्नेंस)

सहायक निदेशक (ई गवर्नेंस)

अमित कुमार
18/4/16

निदेशक (ई.गव)

19/4/16

N14

~~May be~~ same is uploaded on the Website. (http:mohfw.gov.in)

18.4.16

- DIR(eGov.)

19/4

US(eGov)

21/4

AD(e Gov)/ASO

Note No. #2

16/02/2017 10:46 AM

AMIT KUMAR-AD
(AD)

Note No. #3

With the objective to promote standardization and to build interoperability amongst various Health IT Systems in the country, so that a uniform standard-based system for creation and maintenance of Electronic Health Records (EHRs) for citizens could be set-up, MoHFW is undertaking various steps. In this direction, Ministry notified EHR Standards for India in September, 2013. and the revised EHR Standards have been notified in December 2016.

2. With a robust standards compliant EHR system and other health IT systems in place, States/UTs will be able to improve medical record keeping, promote the practice of evidence-based medicine, accelerate research, build effective medical practices, ensure safety etc. to improve the overall quality of health care delivery. It is therefore, proposed that all the States/UTs may be requested to adhere to the notified EHR Standards 2016 for India.

3. Keeping in view the above, a draft letter addressed to Principal Secretary(Health)/Secretary(Health) is submitted for consideration and approval please.

16/02/2017 11:20 AM

S K PANI
(US)

Note No. #4

letter issued

20/02/2017 4:13 PM

JITENDRA ARORA
(DIR)

Note No. #5

07/06/2019 2:53 PM

AMIT KUMAR-DD
(DY.DIR)

Note No. #6

07/06/2019 2:54 PM

ASHISH SHARMA-II(EGOV)
(ASO)

Note No. #7

11/06/2019 11:33 AM

JOGINDER PAL
(US)

Dear ,

Use of ICT in health care (i.e. eHealth) is progressively becoming an integral part of healthcare systems as eHealth has potential to play a transformational role in health care system, especially under the given challenge of ensuring delivery of affordable, cost effective and quality health care to India's billion-plus population. For achieving optimal benefit from eHealth initiatives, focus on an overall framework to set-up an Interoperable Healthcare ICT environment is imperative.

2. With an objective to promote standardization and to build interoperability amongst various Health IT Systems in the country, so that a uniform standard-based system for creation and maintenance of Electronic Health Records (EHRs) for citizens could be set-up, Ministry of Health & Family Welfare (MoHFW) is undertaking various steps. In this direction, Ministry notified EHR Standards for India in September, 2013.

3. Being a living document, with the passage of time the EHR Standards 2013 have been duly revised in line with the contemporary developments in the standards ecosystem in the country as well as globally. The revised EHR Standards have been notified in December 2016 and is available at http://www.mohfw.nic.in/showfile.php?lid=4138.

4. I would like to inform you that in order to facilitate adoption of the entire set of notified EHR Standards in the country, Ministry has decided to engage Centre for Development of Advanced Computing (C-DAC) Pune to set-up and manage "National Resource Centre for EHR Standards (NRCeS)" for providing assistance in developing, implementing and using EHR standards effectively in healthcare applications in India. NRCeS would support National eHealth Authority (NeHA) in due course of time to facilitate adoption of EHR standards for development of an **"inter-operable Health IT ecosystem"** in the country which would lead towards creation of standard compliant EHRs of citizens. NRCeS will also support NeHA in drafting and firming up national roadmap & strategy for adoption of eHealth/mHealth/Telemedicine applications etc. in the country.

5. The current role of interim National Release Centre (iNRC, www.snomedctnrc.in) for SNOMED-CT, which is the primary terminology for all clinical data, will now come under the purview of the newly set-up NRCeS and the current roles/activities performed by CDAC, Pune in capacity of iNRC for SNOMED CT in India will be subsumed by NRCeS with effect from 1st February, 2017.

6. It is informed that India continues to be a member-country of IHTSDO and as decided by the Ministry SNOMED CT remains to be available free of cost to vendors/ developers/ clinical entities for use in India through NRCeS, CDAC- Pune.

7. With a robust standards compliant EHR system and other health IT systems in place, States/UTs will be able to improve medical record keeping, promote the practice of evidence-based medicine, accelerate research, build effective medical practices, ensure safety etc. to improve the overall quality of health care delivery. All the States/UTs are requested to adhere to the notified EHR Standards 2016 for India. In this regard, you are suggested to ensure inclusion of all the relevant clauses required for compliance to the EHR Standards as a prerequisite in RFP/RFQs for all health IT initiatives.

8. In case of any clarification in this regard, Shri Jitendra Arora, Director (eHealth), MoHFW (dir.ehealth@gmail.com); Shri Gaur Sunder, Principal Technical Officer, CDAC Pune (gaurs@cdac.in); or Shri Chandrasen Shrivastava, Project Lead (eHealth), MoHFW (Chandra_works2001@yahoo.com) may be contacted.

With warm regards,

Yours sincerely,

(Jitendra Arora)

To,
Principal Secretary (Health) / Secretary(Health) of all States and UTs.